No. 94-372

In The

Supreme Court of the United States

October Term, 1994

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

MARGARET WHITECOTTON, et al.,

Respondents.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit

BRIEF FOR THE RESPONDENTS

ROBERT T. MOXLEY*
RICHARD GAGE
GAGE & MOXLEY
623 W. 20th Street
Post Office Box 1223
Cheyenne, Wyoming 82003
(307) 632-1112

PROF. PETER H. MEYERS
Vaccine Injury Project,
National Law Center
George Washington University
2000 G Street, Suite 200
Washington, D.C. 20052
(202) 994-7463

JOHN S. CAPPER IV, Esq.
BERRY, CAPPER & TULLEY
P.O. Box 429
Crawfordsville, Indiana 47933
(317) 362-7340

Counsel for the Respondents
*Counsel of Record

62 pp

COUNTERSTATEMENT OF THE QUESTIONS PRESENTED

1. When a petitioner (child) who has a preexisting condition seeks compensation for a vaccine-related injury under the National Childhood Vaccine Injury Compensation Act, and establishes a "Vaccine Table" injury, does the Act create a presumption of compensability and place the burden of proof on the Secretary to rebut this presumption with proof by a preponderance of the evidence that "factors unrelated" to the vaccine caused the child's adverse Table-time reaction?

2. If so, can the Secretary meet her burden by relying on either a) an "idiopathic" pre-existing condition (a condition without a known cause) or b) speculation that such pre-existing condition may have caused the petitioner to have suffered the "Vaccine Table injury?"

TABLE OF CONTENTS

Page

COUNTERSTATEMENT OF THE QUESTIONS PRESENTED i

TABLE OF AUTHORITIES iv

STATEMENT OF THE CASE 1

A. The Vaccine Injury Compensation Proceedings on Behalf of Margaret "Maggie" Whitecotton .. 1

1. Maggie Whitecotton's Clinical History..... 1

B. The Statutory Scheme..... 4

1. The Legislative History of the Act 7

2. The Legislative Definition of "Encephalopathy" 8

3. The Statutory Limitations upon "Factors Unrelated to the Administration of Vaccines" 9

C. The Course of the Case Below..... 10

1. The Initial Decision..... 11

2. Proceedings on Motion for Review..... 14

3. The Second Decision..... 14

D. The Competing Propositions Involved in the Litigation..... 15

1. The Government's Hypothetical Defense – "Organic Brain Syndrome"..... 15

2. The Special Master's Medical Synthesis 16

3. Respondent's Position on Microcephaly in the Claims Court and the Court of Appeals 17

E. The Decision Appealed Herein..... 18

TABLE OF CONTENTS – Continued

Page

SUMMARY OF ARGUMENT..... 20

ARGUMENT ONE: THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT MUST BE "INTERPRETED" TO SAY THAT MAGGIE WHITECOTTON IS CLEARLY ENTITLED TO THE PRESUMPTION OF COMPENSABILITY UNDER THE PROVISIONS OF THE INITIAL VACCINE INJURY TABLE 24

A. The Petitioners' Statutory Burden..... 24

B. The Improper Burden of Proof Imposed..... 25

ARGUMENT TWO: THE STATUTORY CONSTRUCTION URGED BY PETITIONER SHOULD BE DISFAVORED BECAUSE, IF ADOPTED, IT WOULD PRODUCE EFFECTS THAT THE STATUTE WAS INTENDED TO DISCOURAGE 27

ARGUMENT THREE: THE STATUTE IS UNEQUIVOCAL AND CLEAR THAT "FACTORS UNRELATED" MAY NOT BE IDIOPATHIC, HYPOTHETICAL, OR SPECULATIVE..... 28

A. The Secretary Improperly Seeks to Change the Initial Vaccine Injury Table 28

B. The No-Fault Aspects of the Vaccine Compensation Statute Are at the Heart of Legislative Intent..... 30

C. The Secretary and the Department of Justice Would Contradict Their Own Statements in the Legislative Process 32

D. The American Academy of Pediatrics Cannot Deny That the Table Means What It Says..... 34

E. The Federal Circuit Consistently Follows the Rule Below, and Correctly Holds That the Government Must Satisfy an "Actual Causation" Burden of Proof 37

TABLE OF CONTENTS – Continued

Page

ARGUMENT FOUR: MAGGIE WHITECOTTON'S CASE DOES NOT BRING INTO PLAY THE STATUTORY CONCEPT OF "SIGNIFICANT AGGRAVATION." 40

A. There Must be Preexisting **Symptoms** Before There is a "Preexisting Condition" 40

B. "Significant Aggravation" Only Applies To Symptomatic Conditions 41

ARGUMENT FIVE: THE COURT OF APPEALS MUST BE AFFIRMED WITH A DECISION WHICH HONORS THE EXPRESS STATUTORY LANGUAGE AND LEGISLATIVE INTENT 43

A. There is No Legitimacy in an "Interpretation" Exercise 44

B. A Condition Affected By Vaccination Cannot Be A "Factor Unrelated To Vaccine" 46

C. The Vaccine Act Must Be Harmonized With Compensation Law 47

CONCLUSION 50

TABLE OF AUTHORITIES

Page

CASE AUTHORITIES:

Bolinger v. Division of Retirement, State Department of Administration, 335 So.2d 568 (Fla. App. 1976) 47

Bradley v. Secretary of DHHS, 24 Cl. Ct. 641 (1991) 47

Brown, Secretary of Veterans Affairs v. Gardner, ___ U.S. ___, 63 USLW 4035, 1994 WL 687055 (Case No. 93-1128, decided December 12, 1994) 49

Bunting v. Secretary of DHHS, 931 F.2d 867 (Fed. Cir. 1991) 47

Cepeda v. Secretary of DHHS, Case No. 90-2664 (Fed. Cl. Spc. Mstr. July 12, 1994) 41, 42

Chicago City Railway Co. v. Saxby, 23 Ill. 274, 72 N.E. 755 (1904) 46

Ciotoli v. Secretary of DHHS, 18 Cl. Ct. 576 (1989) 40

Costa v. Secretary of DHHS, 26 Cl. Ct. 866 (1992) 42, 48

Costa v. Secretary of DHHS, Case No. 90-1476V (Cl. Ct. Spec. Mstr. Febr. 22, 1992) *remanded* 26 Cl. Ct. 866 (1992) 12, 48

Director Office of Worker's Compensation Programs, U.S. Department of Labor v. Perini North River Associates, 103 S.Ct. 634, 459 U.S. 297 (1983) 49

First Commercial Bank v. Secretary of DHHS, Case No. 90-537V (Cl. Ct. Spec. Mstr., Feb. 25, 1991) 25

Flora v. United States, 357 U.S. 63, 2 L.Ed.2d 1165, 78 S.Ct. 1079 (1958) 44

TABLE OF AUTHORITIES – Continued

Page

Good Samaritan Hospital v. Shalala, 508 U.S. ___, 113 S.Ct. 2151, 124 L.Ed.2d 368 (1993) 49

Hoppin v. Industrial Commission of Arizona, 692 P.2d 297 (Ariz. App. 1984) 41, 43

Huber v. Secretary of DHHS, 22 Cl. Ct. 255 (1990) 42

King v. St. Vincent's Hospital, 502 U.S. 215, 112 S.Ct. 570, 116 L.Ed.2d 578 (1991) 49

Knox v. Secretary of DHHS, Case No. 90-330V (Cl. Ct. Spec. Mstr. Febr. 22, 1991) 11

Knudson v. Secretary of DHHS, 35 F.3d 543 (Fed. Cir. 1994) 10, 39, 40, 41, 42

Koston v. Secretary, Department of Health and Human Services, 974 F.2d 157 (Fed. Cir. 1992) 19, 37, 38

Matter of Compensation of Aquillon, 653 P.2d 264 (Or. App. 1982) 41, 43

Misasi v. Secretary of DHHS, 23 Cl. Ct. 322 (1991) *passim*

O'Connor v. Secretary of DHHS, 24 Cl. Ct. 428 (1991) 12

Pinion v. Board of Retirement, 152 Cal. Rptr. 383 (1979 5th Dist. App.) 47

Pullman-Standard v. Swint, 102 S.Ct. 1781, 456 U.S. 273, 72 L.Ed.2d 66 (1982) 40

Reynolds v. Ruidoso Racing Assn, Inc., 365 P.2d 671 (N. Mex. 1961) 41, 43

Russello v. United States, 464 U.S. 16, 104 S.Ct. 296, 78 L.Ed.2d 17 (1983) 45

Schafer v. American Cyanamid Co., 20 F.3d 1 (1st Cir. 1994) 8, 30

Schumacher v. Secretary of DHHS, 26 Cl. Ct. 1033 (1992) 12

TABLE OF AUTHORITIES – Continued

Page

Schwegman Bros. v. Calvert Distillers Corp., 341 U.S. 384, 95 L.Ed. 1035, 71 S.Ct. 745 (1951) 43

Self v. Starr Davis Co., 187 S.E.2d 466 (N.C. 1972) 41

Silkwood v. Kerr-McGee Corp., 667 F.2d 908 (10th Cir. 1981) 32

Silva v. New England Group, Maremount Corp., 444 A.2d 343 (Me. 1982) 41, 43

Wilson v. Secretary of DHHS, 23 Cl. Ct. 169 (1991) (appealed on other grounds), compensation awarded, Case No. 89-65V, Cl. Ct. Spec. Mstr. January 22, 1991 42

STATUTORY AUTHORITIES:

42 U.S.C. § 300aa-1 28

42 U.S.C. § 300aa-2 (a) (1) 28

42 U.S.C. § 300aa-11 (c) (1) (C) (ii) 5

42 U.S.C. § 300aa-11 (c) (1) (D) (i) 5

42 U.S.C. § 300aa-11 (c) (1) (A) 5

42 U.S.C. § 300aa-11 (c) (1) (B) 5

42 U.S.C. § 300aa-11 (c) (1) (E) 5

42 U.S.C. § 300aa-13 (1) 10

42 U.S.C. § 300aa-13 (2) (B) 10

42 U.S.C. § 300aa-13 (a) (1) (A) 24

42 U.S.C. § 300aa-13 (a) (1) (B) 5, 24, 38

42 U.S.C. § 300aa-13 (a) (2) (A) 5, 9, 19, 38, 45

42 U.S.C. § 300aa-13 (a) (2) (B) 9

TABLE OF AUTHORITIES – Continued

Page

42 U.S.C. § 300aa-14 ..... 28, 38, 47

42 U.S.C. § 300aa-14 (a) 4, 6, 9, 20, 44

42 U.S.C. § 300aa-14 (b) 10

42 U.S.C. § 300aa-14 (b) (2) 23

42 U.S.C. § 300aa-14 (b) (2) (B) 5, 9

42 U.S.C. § 300aa-14 (b) (3) 23

42 U.S.C. § 300aa-14 (b) (3) (A) 6, 9, 40

42 U.S.C. § 300aa-14 (b) (3) (B) 9, 10, 45

42 U.S.C. § 300aa-14 (b) (4) 6, 9

42 U.S.C. § 300aa-14 (c) 28

42 U.S.C. § 300aa-14 (d) 28

42 U.S.C. § 300aa-14 (e) 28

42 U.S.C. § 300aa-15 (a) 40

42 U.S.C. § 300aa-16 7

42 U.S.C. § 300aa-21 (a) 7

42 U.S.C. § 300aa-21 (a) (2) 27

42 U.S.C. § 300aa-33(4) 16, 41

OTHER AUTHORITIES:

22 Am.Jur.2d 233, *Damages* § 283 46

2A *Sutherland Statutory Construction* (5th Ed.) § 45.03 43

TABLE OF AUTHORITIES – Continued

Page

2A *Sutherland Statutory Construction* § 45.05 43

2A *Sutherland Statutory Construction* § 45.07 43

2A *Sutherland Statutory Construction* § 45.08 44

2A *Sutherland Statutory Construction* § 45.10 (5th Ed.) 48

2A *Sutherland Statutory Construction* § 46.01 (5th Ed.) 44

2A *Sutherland Statutory Construction* § 46.06 (5th Ed.) 44

2A *Sutherland Statutory Construction* § 46.07 (5th Ed.) 44

Annotation 85 ALR 2d 1048 47

Annotation 7 ALR 4th 799 47

Annotation 12 ALR 4th 1158 47

American Heritage Dictionary of the English Language (1978) 22, 45

Congressional Record, October 17, 1986, H. 11589 27

Congressional Record, S. 17344-48 33

David S. Fedson, "Adult Immunization: Summary of the National Vaccine Advisory Committee Report," JAMA, Vol. 272, No. 14 (Oct. 12, 1994) 8

Denis J. Hauptly and Mary Mason, "The National Childhood Vaccine Injury Act," Fed. Bar N. & J., Vol. 37, no. 8, pg. 452 7

TABLE OF AUTHORITIES – Continued

Page

"DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis," National Academy Press, 1994 29

Frankfurter, Some Reflections on the Reading of Statutes, 47 Colum. L. Rev. 527 (1947) 43

H.R. 1780 (1986) 30

H.R. 4777 (1986) 30

H.R. 5184 (1986) 30

H.R. 5546 (1986) 33

H.R. 99-908, page 17, USCCAN (1986) page 6358 ..... 27, 29, 30, 42, 49

H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 513, *reprinted*, USCCAN 1989, 3018 30

Kemp, Current Pediatric Diagnosis and Treatment, Ninth ed., chapter 23, page 692 2

Miller, *et al.*, Unreviewed Technical Report, "Parent Reports of DPT Seizure Reactions in Individuals with Tuberous Sclerosis Complex." University of Akron, January 1995 48

Nelson and Duetschberger (Dev. Med. Child Nuerol. 12:487, 1970) 18

Pediatric Neurology, 3rd ed., Harper and Row 3

Restatement (Second) of Torts, Section 433A 27

Restatement (Second) of Torts, Section 433B 27

Rudolph, editor, Pediatrics, 17th ed. 2

RUSCFC Rule 60 (b) 14, 46

TABLE OF AUTHORITIES – Continued

Page

S. 1744 (1986) 33

S. 2117 (1984) 30

S. 827 (1985) 30

S. Hrg. 98-1060, "National Childhood Vaccine-Injury Compensation Act," Hearing before the Committee on Labor and Human Resources, United States Senate, 98th Cong. 2nd Sess., May 3, 1984 ..... 30, 33, 34, 35

S. Hrg. 99-222, "National Childhood Vaccine Injury Compensation Act of 1985," Hearing before the Committee on Labor and Human Resources, 99th Cong. 1st Sess., July 18, 1985 ..... 30, 34, 35, 36

Sells, C.F., "Microcephaly in a Normal School Population." Pediatrics, Vol. 59, No. 2 (February 1977) 18

Serial No. 99-158, "Vaccine Injury Compensation," Hearing before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, United States House of Representatives, 99th Cong. 2nd Sess., July 26, 1986 ..... 30, 37

Signs and Symptoms in Pediatrics, Lippencott 3

Subcommittee on Health and the Environment of the House Commission on Energy and Commerce, 99th Congress, 2d Sess., Childhood Immunizations 103-05 (Comm. Print 1986) 7

Wasserman, Survey of Clinical Pediatrics, 7th ed. 3

No. 94-372

In The

Supreme Court of the United States

October Term, 1994

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

MARGARET WHITECOTTON, et al.,

Respondents.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit

BRIEF FOR THE RESPONDENTS

STATEMENT OF THE CASE

A. The Vaccine Injury Compensation Proceedings on Behalf of Margaret "Maggie" Whitecotton

1. Maggie Whitecotton's Clinical History

Margaret ("Maggie") Whitecotton was born on April 22, 1975. Her hospital records indicated that she was a small but healthy child at birth. Her length and head circumference were in the second to third percentile, and her birth weight was 6 lbs. 7oz., in the 20th percentile. Her growth (weight, head circumference, and length) was monitored in regular pediatric visits, and found to be normal up to age four months. In fact, as the Federal Circuit stated below, "Maggie was healthy, developmentally and physically, until she

received her third diphtherja-pertussis-tetanus (DPT) vaccination on August 18, 1975." Pet. App. 2a.[1]

A great deal of emphasis was placed on Maggie's head circumference in the court decisions below. The circumference of Maggie's head at birth was 12.5 inches or 31.75 cm. *Id.* at 33a. This head circumference placed her in approximately the 2.5 percentile for her age and sex, *Id.* at 32a. In other words, approximately 25 out of every 1000 girls are born with Maggie's head circumference. Statistically, this placed Maggie at the borderline of two standard deviations below the average or "mean" head circumference for a child of the same sex and age. *Id.* at 32a-33a. A baby with a head circumference three standard deviations from the mean would be at or below the 0.35 percentile.

Maggie's condition at birth could be described as "borderline microcephalic". The term "microcephalic" means "small head," and it can range from a borderline condition very close to the average head size to a very extreme condition characterized by a head circumference even 4 or 5 standard deviations from the mean.[2]

---

[1] The following abbreviations are used in this brief:
Pet. App. – Appendix to Petition for Writ of certiorari
Pet. Br. – Secretary's Principal Brief in this Court
JA – Joint Appendix filed in this Court
Tr. – Transcript of proceedings at the hearing below
Exh. – Exhibits introduced at the hearing below

[2] For clinical purposes, microcephaly has been defined by some medical authorities as a head circumference smaller than two standard deviations from the mean, while many other medical authorities – probably the majority – define it as a head circumference smaller than three standard deviations from the mean. Depending on which definition is adopted, Maggie was or was not "borderline microcephalic" at birth. The government's sole medical expert below, Dr. Owen B. Evans, acknowledged that while he considered Maggie to be "microcephalic", Maggie would not be considered "microcephalic" by some accepted definitions of that term, Tr. 247-48, JA at 58. The special master who presided over the hearings characterized Maggie's condition as "at least borderline microcephalic at birth. . . ." Pet. App. 32a-33a. *See also* Kemp, Current Pediatric Diagnosis and Treatment, Ninth ed., chapter 23, page 692 (defining microcephaly as "a head circumference three SD or more below mean for age and sex"); Rudolph, editor, Pediatrics, 17th ed., page 402 ("Most investigators have defined microcephaly as a occipital-frontal circumference (OFC) of less than three standard deviations (SD) below the mean for age and sex."); Pediatric Neurology, 3rd ed., Harper and Row, page 71 ("For standardization, microcephaly is arbitrarily defined by a cranial circumference less than three standard deviations below the normal for age and sex."); Wasserman, Survey of Clinical Pediatrics, 7th ed., page 346 ("Microcephaly . . . the head circumference is always three standard deviations below the mean") Signs and Symptoms in Pediatrics, Lippencott, Chapter 22, page 112 ("There is some disagreement about the clinical definition of microcephaly. The criterion of head circumference more than two standard deviations . . . has been used; measurements three or more standard deviations below the mean have also been recommended.")

Despite her small size, Maggie's medical records showed that she was developing normally, with no sign of any problems, until she began having seizures immediately after she received her third DPT and second oral polio vaccine on August 18, 1975, when she was almost four months old. J.A. at 11.

Maggie began having clonic seizures in her mother's presence about six hours after receiving the vaccines. Pet. App. 27a; Tr. 18-19. Maggie suffered three or four seizures every 20-30 minutes which were characterized by flinching and jerking of Maggie's upper extremities and blinking of her eyes. Tr. 18-19.

Maggie's mother took her to an emergency room that evening, where she was examined by a physician. Pet. App. at 30a. The next morning, Maggie's mother observed the same jerking motions, and she was referred to the chief of pediatric neurology at Riley Hospital. Maggie was admitted and underwent extensive evaluation. The conclusion was that she had suffered a vaccine encephalopathy manifested by her seizures, but appeared otherwise normal from a neurological perspective. The physicians stated that Maggie's seizures "were most likely secondary to the pertussis vaccine which she had received earlier in the day." *Ibid.*

Maggie's development began to slow significantly at this point, including the growth of her head, which slowed so much "that it fell off the growth curve." J.A. 11. Maggie began to lose weight, engaged in projectile vomiting (a possible indication of inflammation of the brain), and she regressed in her ability to raise her feet and hold her head erect. Tr. 26, 30.

Maggie continued to experience a series of seizures over the next several years[3]. In recent years, she "needs constant twenty-four hour monitoring for seizures so that if one develops she can receive the appropriate help." J.A. 14.

Today, Maggie is "disabled both mentally and physically." Pet. App. 37a. She is felt to function at the level of a two to four year old child. Her problems are "compounded by the fact that she is non-verbal and therefore cannot ask questions, talk to other staff or clients, or make her ideas, wants or needs known." J.A. 13. She has cerebral palsy, hip and joint problems, and is not able to walk. Pet. App. 37a. Her condition is stable, and no significant change in her condition is anticipated. She is "for all practical purposes, totally dependent on others for her needs." *Ibid.*

B. The Statutory Scheme

The central feature of the Vaccine Act involved in this case is the Initial Vaccine Injury Table, 42 U.S.C. § 300aa-14 (a). This Table lists certain injuries and conditions, which, if found to occur within a prescribed period of time following vaccination, create a rebuttable presumption of entitlement to compensation. There are two categories of "Table-time" injury, (1) table-time "onset" cases and (2) table-time "significant aggravation" cases. In such cases, the petitioners do not need to adduce proof of actual causation, because causation is presumed. Once the petitioner establishes a prima facie case of Table Injury, and the presumption of compensability arises, the burden then shifts to the government, which must prove

[3] On February 24, 1976, Maggie experienced a major seizure, and was reported unarousable at the hospital. Exh. H-3. On January 16, 1977, Maggie experienced another major seizure, and the hospital admission records voted that she had febrile convulsions. Exh. H-8. On August 28, 1979, Maggie had another seizure. Exh. H-12. Maggie received a DT "booster" shot on March 21, 1980, and the next day she experienced a grand mal seizure. Pet. App. 29a. Maggie's mother testified to additional focal seizures over the next few years. *Ibid.* The last mention of possible seizure activity was noted by the Intensive Care Unit staff at Riley Hospital in 1990 while Maggie was on a ventilator recuperating from major surgery for correction of spasticity-induced kyphosis.

by a preponderance of the evidence that the claimed injury is attributable to "factors unrelated" to the "administration of" the vaccine. 42 U.S.C. § 300aa-13 (a) (1) (B). The Act goes on to indicate that the term "factors unrelated" does not include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. § 300aa-13 (a) (2) (A).

If a petitioner seeks compensation for an injury which is not listed in the Vaccine Injury Table, or for an injury which occurred after the expiration of the prescribed time period following vaccination, the petitioner is not precluded from obtaining compensation. However, for these non-Table Injury cases Congress placed the burden on the petitioner to prove causation in fact. 42 U.S.C. § 300aa-11 (c) (1) (C) (ii). These burdens of proof and presumptions as to causation are a central feature of the Act[4].

The petitioner's Brief sets forth most of the pertinent statutory provisions. However, three significant provisions, (1) the definition of DPT-induced "residual seizure disorder," (2) provisions which link seizures to "encephalopathy," and 3) provisions relating to a child's ultimate outcome, were omitted. Thus, Respondents reproduce the operative language of these sections:

The definition of "residual seizure disorder" is found at 42 U.S.C. § 300aa-14 (b) (2) (B):

> "(b) QUALIFICATIONS AND AIDS TO INTERPRETATION. – The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table . . .

[4] Additional requirements to qualify for compensation under the Act, for both Table and non-Table cases, include: The petitioner's injury must have lasted more than six months, the petitioner must have incurred more than $1,000 in unreimbursed medical expenses, the vaccine must have been administered in the United States, and the petitioner must not have previously collected a damage award in a civil action for the injury. 42 U.S.C. §§ 300aa-11 (c) (1) (D) (i), 300aa-11 (c) (1) (A), (B), and (E).

> "(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion- . . . before the first seizure or convulsion after the administration of the vaccine involved and if . . .
>
> > "(B) . . . the first seizure occurred within three days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after . . . "

The secretary has provided the language of 42 U.S.C. § 300aa-14 (b) (3) (A), the statutory definition of encephalopathy, but omits the pertinent language of § 300aa-14 (b) (4) which states:

> (4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs . . . "

Finally, Respondents rely on the table language in 42 U.S.C § 300aa-14(a) and (a) i.e.:

> "(a) . . . The following is a table of vaccines, the injuries, disabilities, illnesses, conditions and deaths, and the time period in which the first symption or manifestation . . . is to occur . . . for purposes of receiving compensation . . . :
>
> I DPT . . .

Illness, disability injury or condition covered:	Time period for first symptom . . .
* * *	
D. Residual Seizure disorder	3 days
E. Any acute complication or sequela (including death) of an illness, disability, injury or condition referred to above which . . . arose within the time period prescribed	Not Applicable

The Vaccine Act creates a unique federal no-fault compensation program for individuals alleging injury or death due to the administration of one of the mandatory childhood vaccines.[5] Petitions for compensation are adjudicated in the United States Court of Federal Claims. The petition is defended by the Secretary of Health and Human Services, who is in turn represented by the Department of Justice.

The Act took effect on October 1, 1988. Persons alleging injury due to vaccines administered prior to that date have the option of seeking compensation under the Act, or filing a traditional tort suit. Persons alleging injury due to vaccines administered on or after that date are prohibited from filing a civil action seeking more than $1,000 in damages unless the person has first filed a claim under the Act and exhausted its procedures, including rejecting any award of compensation under the Act. *See* 42 U.S.C. §§ 300aa-16, and 300aa-21 (a).

1. The Legislative History of the Act

The Act was prompted by a unique marriage of parents' organizations, vaccine manufacturers, and the public health community. Vaccine manufacturers, citing the costs and uncertainties of defending vaccine claims in civil court, threatened to discontinue vaccine production. Many pharmaceutical companies had already pulled their products at the time that Congress was debating the Act (including two of the three companies marketing the DPT vaccine), and there was great concern that the supply of vaccines in the United States would dry up. *See generally*, Denis J. Hauptly and Mary Mason, "The National Childhood Vaccine Injury Act," Fed. Bar N. & J., Vol. 37, no. 8, pg. 452, 452-53 (1990) [hereafter "Hauptly"].

---

[5] All fifty states and the District of Columbia have enacted laws which generally require proof of immunization before a child enters school. Subcommittee on Health and the Environment of the House Commission on Energy and Commerce, 99th Congress, 2d Sess., Childhood Immunizations 103-05 (Comm. Print 1986). In most states, immunization is required against seven diseases: Polio, measles, mumps, rubella, diphtheria, tetanus, and pertussis. *Id.* at 1.

Parents groups, such as Dissatisfied Parents Together (DPT), were concerned about the extensive delay, substantial costs, and uncertain results of traditional tort actions seeking compensation for vaccine-related injuries. These groups argued that any compensation program must necessarily insure a just and expedited mechanism to protect children who may be injured by adverse reactions to vaccines. *Ibid.*

The public health community was concerned, on the one hand, with the possible withdrawal of vaccine manufacturers, and the consequences that would follow from a lack of supply of vaccines in the United States. These health officials were also concerned, on the other hand, that public confidence in immunization program was being eroded by numerous reported severe reactions (especially to the pertussis vaccine), and the difficulty in obtaining compensation for injured children. These developments, which threatened to substantially reduce immunizations in the United States, were a cause of great concern to the public health community, and were an important motivation behind the vaccine Act. *Ibid.*; *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2-3 (1st Cir. 1994)[6].

2. The Legislative Definition of "Encephalopathy."

The Congressional definitions of injury are couched in medical terminology, but are not always consistent with the way that such terms are used by medical doctors[7]. Of special

---

[6] Currently, 98% or more of American children are fully immunized by the time of school entry. David S. Fedson, "Adult Immunization: Summary of the National Vaccine Advisory Committee Report," JAMA, Vol. 272, No. 14, pg. 1133 (Oct. 12, 1994).

[7] This point is underscored by the discussion in the respondent's report, JA p. 21, at 24. The Respondent's expert acknowledges the "legal question," but then gives a "medical" explanation:

> "As for the legal question of whether this child had a post-immunization encephalopathy, there is no clinical evidence to support an encephalopathy following the immunization such as altered consciousness, focal or diffuse neurologic signs, or other impairment of brain function ***aside from the brief seizures which were observed***. The abnormal disorganization and ***slowing of the EEG could possibly support a diagnosis of encephalopathy***; however, in the clinical picture of co-existing seizures this is not diagnostic." (Emphasis added.)

concern to this case are the **overlapping** definitions of "encephalopathy" and "residual seizure disorder." Encephalopathy **is shown** by seizures, as a matter of law:

> "The term 'encephalopathy' means ***any*** significant ***acquired abnormality*** of, or injury to, or impairment of function ***of the brain***. Among the ***frequent manifestations*** of encephalopathy ***are focal and diffuse neurologic signs***, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, ***with*** or without ***convulsions . . . Encephalopathy*** usually ***can be documented by*** slow wave activity on an ***electroencephalogram***." (Emphasis added.) 42 U.S.C. § 300aa-14 (b) (3) (A)

Even though a "residual seizure disorder" is also a separately defined injury, under 42 U.S.C. § 300aa-14 (b) (2) (B), the key to the finding of a Table injury herein – assuming *arguendo* that the record doesn't have **ample** proof of the residual seizure disorder – is the fact that the case qualifies as an "encephalopathy" under the Table **via the seizures**. They occurred in the statutory "time period in which the first symptom or manifestation of onset . . . is to occur after vaccine administration for purposes of receiving compensation under the program." 42 U.S.C. § 300aa-14 (a).

It is the obvious import of § 300aa-14 (b) (3) (A), quoted *supra*, read together with section 14 (b) (4), that "encephalopathy" embraces seizures, and is conclusively shown by seizure activity.

3. The Statutory Limitations upon "Factors Unrelated to the Administration of Vaccines."

The Secretary in her brief sets forth the passages of the Act which concern "factors unrelated," respectively, 42 U.S.C. § 300aa-13 (a) (2) (A) and (B) (Pet. Br. pp. 3-4) and 42 U.S.C. § 300aa-14 (b) (3) (B) (*Id.* pp. 5-6). But neither the

Secretary nor her *amicus* acknowledge the clear narrowing of the statutory focus where a Table case is concerned. Under the "general rule" of § 13, "factors unrelated" **includes but is not limited to** the listed four categories of "infections, toxins, trauma, or metabolic disturbances." But under the Table, the four listed factors are **exclusive**[8].

Thus, the provisions of § 300aa-13 (1) require the Vaccine Court to make findings as to the petitioner's showing of the elements of the petition, and the absence of factors unrelated. The open-ended recitation in § 300aa-13 (2) (B) that only "includes" the four factors is "(f)or purposes of paragraph (1)." However, when the statute gets to a Table case, it narrows the focus. At 42 U.S.C. § 300aa-14 (b) (3) (B) the Act states,

> "If . . . an encephalopathy ***was caused by*** infections, toxins, trauma ***or*** metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table . . . " (emphasis added).

Speaking of this quoted passage which is from the aids and qualifications to interpretation, the Act at 42 U.S.C. § 300aa-14 (b) states that such provisions "shall apply to the Vaccine Injury Table . . . "

C. The Course of the Case Below.

Petitioners applied for vaccine compensation via a complaint filed on August 2, 1990. On December 21, 1990, the

---

[8] This must account for the apparent confusion in the mind of the *amicus* as it discusses the case of *Knudson v. Secretary of DHHS*, 35 F.3d 543 (Fed. Cir. 1994). *Knudson* is cited as "**allowing**" proof – which the government **could not do** in that specific case – by an "unknown" virus. The cause-and-effect standard of proof properly applied by the Court of Appeals in that case defeated the defense. But the *amicus* fails to acknowledge that the **proof** of cause by unknown virus is **still proof**, of **known causation. Knudson** properly requires that the **mechanism** of causation be shown. Moreover, the *amicus* fails to see the distinction that the statute **allows** proof of alternate causation by "infection" under the Table, via § 300aa-14 (b) (3) (B), but **not** by "idiopathic" factors. *See*, Argument Three, section E, *infra*.

Secretary of Department of Health and Human Services filed a "respondent's report," recommending that the special master deny compensation. The Secretary relied upon the opinion of a Dr. Owen B. Evans, asserting that Maggie Whitecotton suffers a preexisting "organic brain syndrome." (Respondent's Report, page 5, JA at 23). The report acknowledged seizure activity in Table Time, but asserted a failure to demonstrate an encephalopathy. *Id.*, page 6 (JA at 24). The report also asserted that there were not enough seizures to qualify Maggie's condition under the concept of "residual seizure disorder." *Id.*, at 6-7 (JA at 24).

There ensued the routine course of status conferences which precede a decision, and trial if necessary, in these matters. The special master on the occasion of a January, 1991, status conference indicated an inclination to rule for petitioners. Subsequently, petitioners were instructed to begin the life care plan.[9] (See affidavit of counsel in support of amended Rule 60(b) motion, August 25, 1992, see also the Order of September 15, 1992, at page 5, JA at 80). Ultimately, on June 4, 1991, a trial was held in Indianapolis, Indiana.

1. The Initial Decision.

Witnesses for the petitioners were Maggie's mother, Kay Whitecotton; her treating physician, Ellen L. Kitts, M.D.; and Gerald E. Slater, M.D., a pediatric neurologist. Owen Evans, Jr., M.D., was the only defense witness.

The special master's decision issued on the 16th day of August, 1991. The special master's legal analysis was that the alleged "chronic organic brain syndrome . . . which preexisted the administration of the DPT," would be a "factor unrelated" to the vaccine. (Decision, slip opinion at 1, Pet. App. at 25a).

The special master found that Maggie's clinical course of seizures after the third DPT vaccine, on August 18, 1976,

---

[9] The life care plan is ordinarily not initiated before a positive decision on entitlement. The cost of such planning, in the thousands of dollars, is a major administrative concern in the Program. *See, e.g., Knox v. Secretary of DHHS*, Case No. 90-330V (Cl. Ct. Spec. Mstr. Febr. 22, 1991).

would fit within the statutory criteria for a "residual seizure disorder" under section 14 of the Act. (Decision, slip opinion at 2-3, Pet. App. at 27a[10].) However, it was held that this specific condition did not last six months, and is not permanent, thus leading to the conclusion that as of 1991, "she does not presently have a compensable residual seizure disorder." (Decision, page 4, Pet. App. at 30a.) The decision went extensively into analysis of the **cause** of the current overall condition, concluding that it is the result of the preexisting condition, labelled as a "chronic organic brain syndrome." The special master saw Maggie's alleged "microcephaly" as a sign that she "suffered an encephalopathy sometime prior to the administration of the DPT." (Decision, page 7, 33a.)

Having discounted the Table Time seizures as the manifestation of "original injury" at the time of the DPT, the special master embarked upon the application of the "*Misasi* doctrine" which is applied[11] to the question of "significant aggravation" under the Act. Two factors were explored as manifestations of earlier injury, (1) rolling over at a "too early" age, and (2) swallowing problems, denied by the mother but supposedly shown by a treating physician's note (Exh. H-2, p. 3). Implying that Kay Whitecotton was **not** credible, the special master said of the physician's note: "the court considers it credible." (Decision, page 9, Pet. App. at 37a.) The court also stated unequivocally that, "(p)rior to the

---

[10] The special master stated in a footnote, (fn. 4, Pet. App. at 27a), "This conclusion is based on a literal reading of § 14 (b) (2) (B) . . . " The special master went on to speculate that Congress may not have meant what the statute says.

[11] *Misasi v. Secretary of DHHS*, 23 Cl. Ct. 322 (1991), had been affirmed by the Claims Court on June 7, 1991. Its viability and legal correctness has not been settled. It was questioned in *Costa v. Secretary of DHHS*, Case No. 90-1476V (Cl. Ct. Spec. Mstr. Febr. 22, 1992) *remanded* 26 Cl. Ct. 866 (1992), and even partially repudiated by Special Master Baird in a manner approved by the Claims Court in the case of *Schumacher v. Secretary of DHHS*, 26 Cl. Ct. 1033, 1042 (1992). *See also O'Connor v. Secretary of DHHS*, 24 Cl. Ct. 428 (1991), approved by *Schumacher*, which involves a burden-shifting analysis not employed herein.

August 18 shot, Maggie was microcephalic.[12]" However, the Court went on that "beyond that, there were only some hints" of the alleged neurological condition. But, in "predicting the outcome" of the alleged preexisting condition, the special master stated as follows:

> "The fact that there was little evidence of complications of microcephaly prior to August 18, 1975, does not mean that Maggie would have developed normally . . . ***Based on her microcephaly alone, the court is able to predict with a high degree of certainty that Maggie would have been mentally retarded*** even if the DPT vaccine had not been administered to her on August 18, 1975 . . . there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone." (Decision, slip opinion at 10, Pet. App. at 37a-38a, emphasis added.)

The special master accepted the testimony of Dr. Evans, the government's expert, over that of Dr. Kitts, a treating physician. The special master noted agreement between both doctors that all of Maggie's problems stem from a single injury.

Significantly, Dr. Evans revealed on several occasions during his testimony that he does not believe that DPT can cause the type of permanent injury which Maggie has. In fact, Dr. Evans does not believe in **any** kind of DPT-induced permanent neurological injury. (TR at 237-38, 240-41, 286-87, JA at 54, 55, and 61.) Dr. Evans attributed the contemporary diagnosis of post-DPT encephalopathy to the possibility that the medical community **did** believe in the

---

[12] The most significant question under the state of the record is how and whether the alleged headsize puts Maggie into the category of microcephaly. The decision goes scientifically and medically awry, in both factual and legal causation terms, for its failure to distinguish Maggie's borderline microcephaly (at the time of the injury) from the more severe microcephaly from which the special master extrapolated his prognosis in applying the *Misasi* test. The Court should not have to address this mixed issue of law and fact.

existence of permanent DPT injury, at the time of the examinations and work-ups. (TR at 286, JA at 61.)

2. Proceedings on Motion for Review.

Judge Turner of the Claims Court (renamed now to the Court of Federal Claims) affirmed Special Master Baird's decision, by virtue of an opinion dated January 14, 1992. It held that a condition which fits the "Table" definition of "residual seizure disorder" does not **compel** the finding of such a disorder, but that it is discretionary. The court also upheld the special master in "finding that Maggie did not suffer *the sequela* of a residual seizure disorder." (Opinion and Order, slip opinion at 7, Pet. App. at 18a emphasis added.) The Judge of the Claims Court found the decision not to be arbitrary[13].

3. The Second Decision.

The final proceedings in the Claims Court were commenced via the filing of a motion for relief from judgment and for rehearing. This March 30, 1992 motion was amended, and filed with additional exhibits on August 25, 1992.

The additional evidence addressed three points. First, the treating physicians refuted the finding of the "swallowing problem" which was the sole "symptomatic" manifestation of Maggie's alleged preexisting encephalopathy. Second, two treating physicians refuted the idea that Maggie's microcephaly preexisted the shot. Dr. Paul F. Bustion recounted his specific recollection (JA at 71) that Dr. Drew, the diagnosing physician in Indianapolis, had attributed her condition to the DPT. Dr. Foltz, who delivered Maggie, concurred in blaming

---

[13] On all the appeals, the Whitecottons have asserted that the special master was arbitrary. In the RUSCFC Rule 60(b) order, he specifically asserted that the "swallowing problems," one basis of Dr. Evans's opinion, were insignificant to his own findings. (Order, JA at 83-84.) That is, Special Master Baird decided the case "based on the microcephaly alone." Moreover, Dr. Evans' other linchpins were Maggie's seizures, cerebral palsy, and mental retardation, **all of which manifested after the shot.** Transcript at 206, JA at 46.

the DPT, and stated that Maggie was not born microcephalic (JA at 75). Finally, the third point involved a showing by G. Paul DeRosa, M.D., that Maggie's hip problems were not congenital, but secondary to her cerebral palsy (JA at 76).

With the amended motion, petitioners also presented medical literature, from two treatises (Exh. HH and Exh. II). These were to amplify on the theory that the cerebral spinal fluid tests, showing demyelination, were corroborative of an actual adverse vaccine reaction at the time of Maggie's August 18, 1975 vaccination.

The matter was referred to the special master, and on September 15, 1992, the special master entered an order finding that all evidence but the letter from Dr. Bustion could have been discovered pretrial, and thus was not newly-discovered. None of the evidence, according to Special Master Baird, would change the result.

The Claims Court upheld the denial of the motion, and the appeal to the Federal Circuit, which had been stayed, resumed, with a separate appeal of the denial of the Rule 60(b) motion.

D. The Competing Propositions Involved in the Litigation

1. The Government's Hypothetical Defense – "Organic Brain Syndrome."

To initially put the case in issue, the Secretary of Department of Health and Human Services filed a "respondent's report," dated December 21, 1990, recommending that the Office of Special Masters deny compensation for Maggie Whitecotton. The Secretary relied upon the opinion of Dr. Owen B. Evans, asserting that Maggie Whitecotton suffers a preexisting "organic brain syndrome." (See Dr. Evans' Report, JA at 21). The report acknowledged seizure activity in Table Time, but asserted a failure to demonstrate an encephalopathy[14]. (*Id.*, JA at 24)

---

[14] Dr. Evans was cross-examined about his bias, shown *inter alia* by his statement (JA at 24) that no studies show a relationship between immunizations and

At trial, the Secretary's counsel proceeded from the assumption that "microcephaly" is a ***disease***, posing questions about disabilities whose "etiology" is "microcephaly." (Transcript at 88-89, Transcript at 207, JA at 46.)

According to her treating physician, Dr. Ellen Kitts, Maggie Whitecotton was **not** born with Cerebral Palsy, which is the expression of her vaccine related encephalopathy. There is **no evidence** of any defined causation process, other than an adverse reaction to vaccination, which produced the actual disability. The Respondents have asserted throughout that the special master in this case equated a questionable, borderline microcephaly with a major, full-blown disorder, ignoring a marked discontinuity of development **and** head growth, post-vaccination[15].

2. The Special Master's Medical Synthesis.

The special master saw Maggie's alleged "microcephaly" as a sign[16] that she "suffered an encephalopathy sometime prior to the administration of the DPT." (Decision, page 7,

---

chronic or progressive neurologic disease. The special master came to his defense (TR 286-87), asking if his bias would prevent him from stating that there was or was not an encephalopathy in Table time. The doctor stated that it would not. However, Dr. Evans claimed there was no encephalopathy, despite the Table-time seizures, and abnormal EEG. (JA at 24.)

[15] As suggested by the secretary, the special master's significant aggravation analysis stated that "there was no dramatic turn for the worse in her condition indicating a permanent aggravation." Decision, Pet. App. at 42a. This is in the eye of the beholder, although the sufficiency of her case is a matter of law. Her present condition, compared to her condition before the shot, is obviously one of "markedly greater disability, pain or illness, accompanied by substantial deterioration of health." *See* 42 U.S.C. § 300aa-33 (4). And she was contemporaneously diagnosed with vaccine encephalopathy, certainly dramatic to her parents and treating physicians.

[16] In actuality, the special master used Maggie's **post-DPT** fall-off from the head size curve to corroborate his finding of pre-shot injury. The special master first discussed the head size up to the time of the shot, but stated, "(i)n the succeeding months, Maggie's head growth fell further behind the norm . . . "

Pet. App. at 33a.) The Court of Appeals acknowledged[17] **the special master's findings** as logically pointing to some other cause for her difficulties. Opinion, Pet. App. at 8a. But the special master could not say whether DPT caused or aggravated Maggie's cerebral palsy.

On the appeal below, the "Statement of Issues" in the Whitecotton's brief featured *inter alia* the following question:

> "3. MAY A SPECIAL MASTER FORMULATE HIS OWN OPINIONS ON MATTERS OF ULTIMATE MEDICAL FACT?"

The Whitecottons made various criticisms of the special master's reasoning. They asserted that "Special Master Baird's finding that the mental retardation was 'inevitable' is purely a matter of statistical analysis of head size as the proof of the defense." There was no such statistical analysis from an expert in the record. The Whitecottons also asserted that Special Master Baird called the evidence of swallowing problems "insignificant." (See Order, September 15, 1992, page 4, JA at 85.) In stark contrast, Dr. Evans stated that the head size and swallowing problems were the **only** signs of the chronic organic brain syndrome.

The Whitecottons asserted that it is improper for the special master to have found support from Dr. Slater, petitioners' expert, for the proposition that Maggie was microcephalic prior to the shot. The argument was made that it is not fair for the special master to give the facts significance which the expert does not[18].

3. Respondent's Position on Microcephaly in the Claims Court and the Court of Appeals.

The Whitecottons also took Special Master Baird to task for ignoring expert testimony **and** the import of medical

---

[17] It was obviously irrelevant to the Court of Appeals that the factfinding was suspect, since the obviously idiopathic "factor unrelated" was **legally** irrelevant.

[18] The special master derived insights from the testimony of the treating physician, Dr. Kitts, with which she would most obviously disagree. And Dr. Slater clearly placed the most reliable indicators of microcephaly at a point several months later, far enough post-DPT for the shot to have been the cause.

literature filed by the petitioners (Exhibit S[19]). They made an unrebutted showing that children who fit the loose, most inclusive definition of microcephaly – adopted by the Court[20] – can indeed **as likely as not** be completely normal.

The Whitecottons pointed out a clinching factor in the analysis employed by the special master. This is the indisputable fact that there are **thousands** more children who fit the borderline definition of microcephaly (-2 SD below the mean), than who fit the more standard definition (-3 SD or more from the mean). It was pointed out that if the mild microcephaly exhibited by Maggie Whitecotton prior to her shot were **indeed** accompanied by a 90% chance of mental retardation, then such small-headed people would make up the **vast majority** of mentally retarded people[21]. This ultimate extension of the special master's reasoning is a fact which is simply not true, cannot be proven, and can be **disproven** with resort to any honest scientific inquiry. No authority **anywhere** would extrapolate Maggie's pre-shot head size into a 90% chance for mental retardation.

E. The Decision Appealed Herein.

The United States Court of Appeals for the Federal Circuit reversed, ruling unanimously that Maggie was entitled to compensation in this case. The Court held first that Maggie had suffered a Table Injury – an encephalopathy which manifested itself in the form of seizures occurring within the Table time after vaccination. Pet. App. 6a-7a. The court indicated

---

[19] Sells, C.F., "Microcephaly in a Normal School Population," Pediatrics, Vol. 59, No. 2 (February 1977). The study notes a paucity of research regarding microcephaly in normal populations, and cites Nelson and Duetschberger (Dev. Med. Child Nuerol. 12:487, 1970) as a source of a 50% risk figure.

[20] As graphically demonstrated by the chart in the Joint Appendix at page 65, Special Master Baird adopted a definition even looser than the government's expert.

[21] See the Argument set forth in the Brief in Opposition to the Secretary's petition for *certiorari*, September 30, 1994, at section I, subsection A, entitled **"Maggie Whitecotton's So-Called State of 'Microcephaly' Prior to the Shot Has No Medical Significance."** Therein, Respondents conclusively demonstrate that the Special Master's statistical analysis is scientifically invalid.

that because Maggie had shown a Table Injury, she was entitled to "the benefit of the Act's presumed causation," Pet. App. 7a, and the burden was on the government to prove that Maggie's injuries were caused by "factors unrelated" to the vaccine. *Ibid.*

The Federal Circuit then went on to hold that the government had not met its burden of proof, for two separate and independent reasons. First, the Court applied the statutory provision that a "factor unrelated" cannot include any "idiopathic" condition. Pet. App. 7a, citing 42 U.S.C. § 300aa-13(a)(2)(A). An "idiopathic" condition is one of unknown cause, and all parties below agreed that the cause of Maggie's microcephalic condition was unknown. The Court below cited its prior decision in *Koston v. Secretary, Department of Health and Human Services*, 974 F.2d 157 (Fed. Cir. 1992), which discussed this provision in detail. *Koston* and its progeny have held that such preexisting conditions as Rett Syndrome and Sudden Infant Death Syndrome (SIDS), which have no known cause, cannot defeat Table Injury claims.

The court below also held that the government had not met its burden of overcoming a Table Injury because it had relied upon pure "speculation" that Maggie's pre-existing microcephaly caused her current condition. Pet. App. 8a-9a. The court indicated that at the hearing below, the government called only one expert, Dr. Owen B. Evans, who "could only speculate that Maggie suffered a brain injury at some time before she received the vaccine in August 1975." *Id.* at 8a. The lower courts had erroneously adopted this speculation of Dr. Evans, undercutting the key presumption Congress had placed in the Act for Table Injury cases. *Id.* at 9a. The Federal Circuit concluded that a Table Injury presumption of causation could not be overcome by:

> "speculative or hypothetical matters or explanations" of alternate causation; under the Act, a Table Injury must be presumed vaccine-related unless ***demonstrated to arise*** from "other defined illnesses or factors." *Ibid.* (emphasis added) (citation omitted).

SUMMARY OF ARGUMENT

The Court in this matter should honor its traditional and appropriate hesitation to re-write legislation in the name of interpretation. The critical aspect of this case is the ***legal*** definition of the quasi-medical terminology of the Act.

And so a primary task in making sense of this appeal is to compare the Act, its language and intent, with the substantive basis of the special master's erroneous Decision. One great problem associated with this case (and many cases in the Office of Special Masters) is the refusal of the Secretary or the court to recognize that "acute complications **or** sequela[22]" of encephalopathies are Table Injuries also, with no time limit applicable for their manifestation. Thus, there was a violation of the statutory presumption of compensability where the special master looked for cause and effect between the seizures and the sequela of encephalopathy, that is, Maggie's current condition.

The specific doctrine[23] which was applied to defeat the claims of Maggie Whitecotton at the trial level violates the clear will of Congress as embodied by the "no-fault" National Childhood Vaccine Injury Compensation Program.

The statutory application of the Court of Appeals below – not its first, nor its latest, where the same issue is presented – pronounces a badly-needed correction.

The Secretary of Health and Human Services and her *amicus curiae* ally participated in the legislative process, and

---

[22] As a matter of proper understanding, "acute" does not modify "sequela." A "complication" is by its nature acute, while a sequela is chronic. Maggie Whitecotton's cerebral palsy is an **undeniable** sequela of an encephalopathy. So is retardation.

[23] See the recitation by Judge Turner at Pet. App. 21-22a and discussion by the special master from 36a through 43a. The *Misasi* rule requires a petitioner in a Table "significant aggravation" case to prove that the child would **not** have developed the same ultimate condition, absent the Table-time encephalopathy. This repudiates the express statutory provision of 42 U.S.C. § 300aa-14 (a) I E which lists complications and sequela of DPT encephalopathies as Table illnesses – of equal dignity to the initial encephalopathy or seizure disorder – "for purposes of receiving compensation under the Program."

predicted the result below as a consequence of the specific language of the Act[24]. Yet, the Secretary vigorously protests her statutory burdens and the statutory limitations on her defenses.

Both pillars of the Secretary's appeal will crumble in the light of scrutiny. The Secretary invokes "interpretation" without showing the presence of ambiguity. Her resort to indications of congressional intention is limited, secondary, selective and misleading. And the Secretary would interpret the Act in a manner which rejects its explicit categories.

The burden is the key. The statute imposes a burden of showing "significance" for an aggravation case. But the "residual seizure disorder" – an "onset" injury – is significant as a matter of law. Thus, too high a burden may be imposed on a child like Maggie, and it follows that an even higher – well nigh **impossible** – burden is placed on petitioners in legitimate significant aggravation cases.

The second argument invokes but does not embody "logic." The Secretary avers that her expert's hypothetical preexisting condition – supposedly shown by Maggie Whitecotton's small head – makes it "logically impossible" that the vaccine could have injured her. But there is unrebuttable evidence – medical test results – which documented an acute brain injury at the time of vaccination[25].

Similarly, the *amicus curiae* brief presents an illogical policy argument. The assertion will not withstand scrutiny that the Court of Appeals' construction of the statute is "medically unworkable." There may be little reason to debate

---

[24] Petitioners will demonstrate, *infra*, numerous statements of position by the Secretary and its allies in the medical establishment, made during the legislative process. The Petitioners and the Justice Department clearly foresaw the consequences of the Act in its final proposed form, which they now lament. Before passage, the **same** lament was, "this is what will happen if you pass the Act this way." Now, it is disingenuous for the Petitioners to urge "If you **enforce** the Act this way, this is what will happen." They should not be heard to say that the Act does not mean what they **know** it says, and **said** it meant.

[25] See, *e.g.*, the letter from Dr. Bustion to counsel, JA at 63-64, discussing acute demylinating changes in CSF.

whether or not "idiopathic[26]" is broad or narrow; the Court should recognize and hold that the Secretary may not look beyond the **allowable** statutory concepts for "factors unrelated." Unless there is **documentable** evidence of **actual** causation by "infections, toxins, trauma, or metabolic disturbance," the inquiry is at an end. It is not a material dispute for trial where the Secretary goes outside the statute in the defense of an obvious "Table" case[27].

The Table time reaction **is in fact** the "first" manifestation of the "injury, illness, condition, disability or death" which the Act regards as a vaccine injury. One cannot aggravate that which is not already manifested by pain, illness or disability.

The only way an alternate **actual** cause can truly be shown is with reference to identified, temporally-significant **exposure** to outside agents. The *amicus* even admits that "where an event frequently associated with neurologic damage is known to have taken place, it cannot be

---

[26] In point of fact, the Federal Circuit itself used a narrow definition of the word. Reviewing a general dictionary, we find the following:

> "**id-i-op-a-thy** . . . *n. Medicine.* **1.** A disease of unknown origin or cause; a primary disease. **2.** A disease for which no cause is known. – **id-i-o-path'ic** *adj.*" *The American Heritage Dictionary of the English Language* (1978)

In *Stedman's Medical Dictionary* (25th Ed.) we also find,

> "**idiopathic** . . . Idiopathetic. **1.** Agnogenic, denoting a disease of unknown cause. **2.** Denoting a primary disease.
> * * *
> "**primary** . . . **1.** The first or foremost, as a disease or symptoms to which others may be secondary or occur as complications."

[27] The AAP seems to perceive that the policy to encourage vaccination is thwarted by Table Case no-fault compensation. They must fear that the concrete experience under vaccine compensation law will make the DPT vaccine appear to be a defective product; they also fear that children with neurologic disorders will not be vaccinated as "recommended." *Amicus* brief at page 15. But the counterargument certainly avails. Concerned parents will most **certainly** hesitate to vaccinate their children if the government refuses to be responsible for apparent vaccine injuries.

predicted with any degree of certainty that the child in question was injured . . . " *Amicus* brief at 14[28].

Upon whomever is placed the burden, is placed the effect of practical reality: nobody can predict what will happen in the individual case. But to enforce "no-fault" compensation this Court must require that the Secretary, under the statute, document and explain the presence and import of an alleged preexisting condition. "Microcephaly" – a non-specific diagnosis – does not qualify under the statute, either as a preexisting condition or as an alternate cause. Nor does the record support the assertion that Maggie Whitecotton's head size had **any** medical significance to an "onset" case.

It should be the holding of this Court that to show a preexisting "encephalopathy," the Secretary must demonstrate an illness which meets the **statutory** definition of encephalopathy. It is not proper that the Secretary be allowed to ignore the fact, in the case of Maggie Whitecotton, that a small head is not a symptom[29] of disease.

It is necessary that the Court be exposed to the legislative process as an indicator of legislative intent. More importantly, it is necessary that this court review the legal reasoning and doctrines which place **all** Vaccine Act petitioners at a disadvantage. Only with a clear understanding of the way in which the Vaccine Court ignores and violates the express terms and spirit of this important legislation will this Court be able to enforce the statute, deliver justice to Maggie Whitecotton, and in so doing promote the important policies which underlie the Act.

---

[28] The *amicus* also acknowledges that individual children may be "stronger or weaker than most." *Ibid.* This is **not** an argument for abandoning Table treatment of injuries.

[29] The "finding" of a preexisting encephalopathy is to be reviewed *de novo*. It is a question of law, of whether or not the condition meets the specific legal definitions of encephalopathy under 42 U.S.C. § 300aa-14 (b) (2) and (3).

ARGUMENT ONE: THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT MUST BE "INTERPRETED" TO SAY THAT MAGGIE WHITE-COTTON IS CLEARLY ENTITLED TO THE PRESUMPTION OF COMPENSABILITY UNDER THE PROVISIONS OF THE INITIAL VACCINE INJURY TABLE.

A. The Petitioners' Statutory Burden.

> "The Vaccine Act . . . tries more quickly to deliver compensation to victims, while also reducing insurance and litigation costs to manufacturers. The Act establishes a special claims procedure involving the Court of Federal Claims and special masters (a system we shall call the "Vaccine Court.") ***A person injured*** by a vaccine may file a petition with the Vaccine Court to obtain compensation (from a fund financed by a tax on vaccines). He ***need not prove fault. Nor***, to prove causation, ***need he show more than that he received the vaccine and then suffered certain symptoms within a defined period of time***." BREYER, C.J., in *Schafer v. American Cyanamid Co., supra,* 20 F.3d at 2-3 (1st Cir. 1994) (Citations omitted, emphasis added.)

The statute explicitly defines the Petitioner's burden in terms of the elements of the Petition. In the Act at 42 U.S.C. § 300aa-13 (a) (1) (A) and (B), Congress incorporated by reference the elements of a Petition. The plain statement in the statute, the "general rule," (see full text, Pet. Br. page 3) is that " . . . ***Compensation shall be awarded . . . if . . . the petitioner has demonstrated . . . the matters required in the petition*** and . . . (t)here is not a preponderance of the evidence that the illness, disability, injury, condition, or death[30] described in the petition is due to factors unrelated to the administration of the vaccine described in the petition."

---

[30] It is significant that the Act **repeatedly** describes vaccine injury with this combination of terms, **all of which denote the absence of good health.**

The holdings of the lower courts, *e.g.*, in placing a burden to apportion between even a latent "preexisting condition" and the apparent sequela of the acute illness described in the petition, are therefore suspect.

B. The Improper Burden of Proof Imposed.

The doctrine which infects the judgment below was created from whole cloth by Special Master Paul Baird, in the case of *First Commercial Bank v. Secretary of DHHS*, Case No. 90-537V (Cl. Ct. Special Master, Feb. 25, 1991). Then the doctrine was adopted wholesale by Special Master LaVon French, in the case of *Misasi v. Secretary of DHHS*, and when, as it inevitably will in almost any case, it foreclosed the petitioner from recovery, it was reviewed by the Claims Court, and upheld in *Misasi v. Secretary of DHHS*, 23 Cl. Ct. 322 (1991). The doctrine was promulgated in these cases **without any citation of supporting authority.** It is now frequently referred to in vaccine practice as the "*Misasi* rule."

The *Misasi* formulation of the rule is found at 23 Cl. Ct. 324, and is repeated verbatim by Judge Turner herein (Pet. App. 21-22a):

> "To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's preexisting condition, (2) assess the individual's current condition after the administration of the vaccine, (3) ***predict the*** individual's ***condition had the vaccine not been administered***, and (4) ***compare the*** individual's current ***condition with the predicted condition*** had the vaccine not been administered." (Emphasis added.)

In simple terms, the *Misasi* doctrine is a repeal of the presumption of causation which is the central feature of the no-fault Vaccine Act compensation scheme. In terms of more complex legal analysis, the doctrine is a confusion between medical cause and legal cause, an aberration in the law of compensation. That is, compensation law has **always** found

legal cause in the concepts of "triggering" or "lighting up," and the Vaccine Act embodies those concepts in its definition of injury as being an ***association*** between the vaccine and the disability in question. While Congressional intent clearly is to dispense with difficult causation problems, the thrust of the *Misasi* doctrine is to require proof of actual causation before these petitioners, despite "Table Injury," can recover. The absurdity lies in the fact that almost any vaccination which implicates the *Misasi* doctrine would have been, by definition, contraindicated, had the so-called preexisting condition been recognized at the time.

The *Misasi* doctrine has resulted in an inappropriate confusion, whereby the statutory concept of "factors unrelated to vaccine" is extended to embrace the not only idiopathic disorders, but also the individual weaknesses of children which may make them susceptible to vaccine injury. These weaknesses in latent form prior to immunization are being improperly equated to preexisting encephalopathies, and parents are required to follow incorrect significant aggravation doctrine in "onset" cases. Parents face the same actual causation burden in legitimate significant aggravation cases.

Thus, the parents of the susceptible child who is outwardly completely healthy at the time of immunization must nonetheless speculate to predict **fully at their own risk,** whether to be confident in administering the shots. If there is an injury, there is no relief. The child with a predisposing disorder must **prove** that it would not have become serious. This he cannot do.

The articulation of the *Misasi* doctrine is a retrenchment, and a retreat from at least five decades of modern doctrine. The idea that an injured party must both qualify and quantify a preexisting condition, even if it is completely latent, is completely unique in the compensation law of modern jurisprudence[31]. Moreover, the doctrine is contrary to the well-developed common law of torts, which imposes the burdens on the defense, and requires a specific sequence of inquiries,

---

[31] See the rendition of compensation law in Arguments Four and Five, *infra.*

even where the preexisting condition is already symptomatic. *See*, Sections 433A and 433B of the Restatement (Second) of Torts.

Misasi undermines a major purpose of the Vaccine Program, which is to foster confidence and participation in the mandatory childhood immunization effort. Without the certainty of compensation, the "speed and reliability with which the petitioner can expect judgment," Congress recognized that "the compensation system would work an injustice on the petitioner." H.R. 99-908, page 17, USCCAN (1986) page 6358.

Unless all children, including predisposed children, are presumed to be injured, the purpose of the Act is frustrated. Clearly, the Table creates the same presumption for causation in significant aggravation cases as it does for "onset" cases. All that is required is to demonstrate the illness in Table Time which the Act envisions. "Significant aggravation" must be **written back into** the Act.

The *Misasi* rule might just as truly be termed the "*Whitecotton*" rule, if the special master's Decision were to be reinstated herein. But by any name, it is totally at odds with the statutory scheme. The *Misasi* rule should be forcefully repudiated by this Court.

ARGUMENT TWO: THE STATUTORY CONSTRUCTION URGED BY PETITIONER SHOULD BE DISFAVORED BECAUSE, IF ADOPTED, IT WOULD PRODUCE EFFECTS THAT THE STATUTE WAS INTENDED TO DISCOURAGE.

Petitioner's argument would deny Maggie Whitecotton compensation and leave her no further recourse except in the tort system. Under the law, her right to sue the vaccine manufacturer in tort is preserved. See 42 U.S.C. § 300aa-21(a)(2).

The two principal purposes of this statute, however, were to "protect the adequacy of the Nation's supply of vaccines" and to "compensate those children who are injured by side effects or reactions to those vaccines." Congressional Record,

October 17, 1986, H. 11589 (daily ed., statement of Rep. Waxman upon final passage.)

Both of these purposes would be thwarted by the adoption of construction of the statute urged by the Secretary and her amicus. Maggie and others similarly situated would be left with no alternative, but to initiate tort litigation; this is what the Act sought to discourage by making available no-fault compensation.

Under these circumstances, such an interpretation should be disfavored. Only if the plain meaning of the Act compels such a result should the Court consider adopting a statutory construction which is plainly at odds with the stated policy goals to be achieved by the Act.

This is not such a case. In this case, the plain meaning of the law would further these main underlying purposes, and result in compensation for Maggie Whitecotton.

ARGUMENT THREE: THE STATUTE IS UNEQUIVOCAL AND CLEAR THAT "FACTORS UNRELATED" MAY NOT BE IDIOPATHIC, HYPOTHETICAL, OR SPECULATIVE.

A. The Secretary Improperly Seeks to Change the Initial Vaccine Injury Table.

The table of injuries set forth at 42 U.S.C. § 300aa-14 has one aspect not yet emphasized in these proceedings. It is the "***Initial*** Vaccine Injury Table." (Emphasis added.) Because there is a specific design for the way the Table may be changed, any debate about the incidence of "real" vaccine injuries, or the policy concerns raised by the *Amicus*, are to be addressed under the Act itself. The Courts should not be involved.

At 42 U.S.C. § 300aa-2 (a) (1) the Act contemplates research on vaccines, as more fully amplified upon in a note to 42 U.S.C. § 300aa-1. As clearly set forth at 42 U.S.C. § 300aa-14 (c), (d) and (e) the Table may be amended by the Secretary, with input from the Advisory Commission on Childhood Vaccines. The Secretary may also recommend changes in the Table to Congress. But the presumption of

compensability arising from the Table is to be honored in the interim:

> "The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information . . . ***Until such time***, however, ***the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.***" (emphasis added) H.R. 99-908, page 18, *reprinted*, USCCAN at 6359 (1986)

Research called-for by the Act, with respect to DPT, has been completed. Certain of that research is even cited by the *amicus* in its brief at page 15, footnote 41. But the picture is not whole without "DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis," National Academy Press, 1994. Therein, the Institute of Medicine concludes at page 11:

> "* * * ***the balance of evidence is consistent with a causal relation*** between DPT and the forms of chronic nervous system dysfunction described in the (National Childhood Encephalopathy Study, commonly referred to as the "NCES[32]") in those children who experience a serious, acute neurologic illness within 7 days after receiving DPT vaccine."

---

[32] Originally, the IOM was critical of causation inferences being based upon the NCES. With its May 2, 1994 report, it changed its tune. Thus, the IOM has finally verified the basis of the statutory presumptions set forth in the original language of the Act. At trial herein, the government's expert implied, speaking of the "British study," that the NCES meant nothing, and maintained that there is no evidence to support the concept of permanent injury by vaccine reaction.

B. The No-Fault Aspects of the Vaccine Compensation Statute Are at the Heart of Legislative Intent.

> "Respondents have . . . mounted defenses incompatible with a no-fault system of compensation." – Congressional criticism stated in H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 513, *reprinted*, USCCAN 1989, 3018, 3116.

The opinion in *Schafer v. American Cyanamid, supra,* notes that the Act was passed when *inter alia*, injured persons complained about the uncertainty, delay and cost[33] of tort litigation. Meanwhile potential tort defendants complained of litigation expenses, occasional large recoveries, and the increased cost of doing business. *Id.*, 20 F.3d at 2.

That the Vaccine Act is a "tort reform" is clear. (See the comments of the House Energy and Commerce Committee in House Report 99-908, pages 4-7, "Background and Need for Legislation"). In the long process during which this type of legislation was under study, number of parties, including the Department of Health and Human Services and the American

---

[33] A number of Legislative proposals were actively debated. The Vaccine Injury Table was a central feature in S. 2117, introduced by Senator Hawkins (R. Fla.) and debated in 1984. *See*, S. Hrg. 98-1060, "National Childhood Vaccine-Injury Compensation Act," Hearing before the Committee on Labor and Human Resources, United States Senate, 98th Cong. 2nd. Sess., May 3, 1984. (The record of this proceeding will hereinafter be cited as "1984 Senate hearing, page ___.")

The Table was set forth again in S. 827, introduced by Senator Hawkins (R. Fla.) and debated in 1985. *See*, S. Hrg. 99-222, "National Childhood Vaccine Injury Compensation Act Of 1985," Hearing before the Committee on Labor and Human Resources, 99th Cong. 1st Sess. July 18, 1985. (The record of these proceedings will be cited hereinafter "1985 Senate hearing, page ___.")

After S. 2117 and S. 827 were killed, in the presence of strong opposition from the executive branch, the AMA and the vaccine manufacturers backed, respectively, H.R. 1780 and H.R. 4777. These bills were debated along with H.R. 5184, in 1986. None of these bills passed, but all contained the Table. Their tort reforms and disregard of such issues as at-home care caused them to be unacceptable to the Dissatisfied Parents Together. *See*, generally, Serial No. 99-158, "Vaccine Injury Compensation," Hearing before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, United States House of Representatives, 99th Cong. 2nd Sess., July 26, 1986. (The record of these proceedings will be cited hereinafter as "1986 House hearing, page ___.")

Medical Association, sought to preempt all rights of petitioners to sue vaccine makers in court. DHHS was among the first seeking to provide this compensation program as an **exclusive remedy** for vaccine injuries. For instance, in his testimony before the Senate Committee on Labor and Human Resources, Dr. Edward Brandt (Assistant Secretary of Health, DHHS) stated,

> "There are numerous additional problems with the program that (Senator Hawkins' bill) would establish, and I will mention some of them. The proposed program does not represent an exclusive remedy; individuals may choose whether to pursue the tort system or the compensation system. This provision is inconsistent with one of the major stated purposes of the bill, which is to relieve the pressure of litigation on vaccine manufacturers." 1984 Senate hearing, page 18.

But consistent with the early principles[34] presented by Dissatisfied Parents Together, Congress chose to solve the problem by making the Program an **attractive** alternative to the tort system, one which parents would **want** to pursue in lieu of the tort system.

On one hand, it is true that pediatricians and manufacturers are not **completely** immune under the Act. But then again, the Program will require the parents of Maggie Whitecotton to spend over ***five years*** in the pursuit of justice for their child.

The immunity provided to pediatricians and manufacturers is a clear parallel to the immunity classically provided to employers by Workmens' Compensation. Liberal interpretation of compensation legislation, and broad coverage, is

---

[34] Principle No. Three, as set forth in the testimony of Jeffrey H. Schwartz, President, Dissatisfied Parents Together, stated:

> "The bill must not restrict in any way a parent's (or child's) right to sue under existing law. The choice as to whether to sue under existing law or to seek this new form of compensation should belong entirely to the parents." 1984 Senate hearing, pp. 49-57.

the trade-off for such immunity[35]. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 667 F.2d 908, 916 (10th Cir. 1981).

While it is true that a typical workmans' compensation statute provides the employer more "consideration" in the bargain, because it provides full immunity and completely prohibits the resort to civil actions, this does not mean that the injured child has less right to consideration in this system. The injured worker knowingly and voluntarily exposes himself to the hazards of the workplace, and gets **paid** to do it. But the child to be vaccinated has no choice in the matter. He is doing his "duty" for the greater good, and could be killed in action. And his parents know that he can't be allowed into school without enduring the unconsented-to insult of the shot, an imposition upon the child that would constitute a battery at common law. And so the Act is fully as much a trade-off to be enforced, such that apparently injured children should be compensated without regard to fault, no less than the injured worker under the many compensation systems which are in place in this country.

C. The Secretary and the Department of Justice Would Contradict Their Own Statements in the Legislative Process.

While it is not the purpose of the Respondents to advocate that this court "search out" the intent of Congress, Respondents submit that such an exercise will completely refute the assertions of the Secretary and her *amicus*. The Justice Department and the Department of Health and Human Service originally opposed enactment of the Act on the

---

[35] Denial of compensation in cases like Maggie's is a threat to the manufacturers. Denying compensation in "significant aggravation" cases is likewise a threat to pediatric medicine. Two of the three petitioners in the triad of special master cases which led to *Misasi* decided to pursue a civil remedy, without even motion for review. (Source: telephone calls with petitioners' counsel.) Denying compensation to a child whose shots were somehow ill-advised will clearly promote malpractice cases. And it especially makes no sense that "significant aggravation" treatment should be denied to the apparent victims of the predicted response to a contraindicated shot. The problem is doctrines which place no real burden on the Secretary, and, conversely, require petitioners to prove causation.

ground that it would create a strong presumption of causation by vaccination. No less than five examples of this opposition are found in the legislative history.

Thus, on October 18, 1986, in the Congressional Record, S. 17344-48, statements of Senators Hatch, Quayle and Dole voice Justice Department and White House opposition to the vaccine compensation bill.[36]

On October 3, 1986, a letter was written from the Assistant Attorney General, Office of Legislative and Intergovernmental Affairs, United States Department of Justice. Addressed to Peter W. Rodino, Chairman, House Committee on the Judiciary, the letter opposed enactment of H.R. 5546 – the text of which was grafted onto S. 1744 (1986), which was enacted. Then on October 7, 1986, a letter was forwarded to Speaker of the House, Thomas P. O'Neill, from Secretary of DHHS Otis W. Bowen, M.D., opposing the final bill. *Inter alia*, the letter voiced opposition to the legislation because of the "table of compensable injuries and interpretive provisions."

Years before the legislation was reported out of Committee, the Secretary and the Department of Justice were opposed to the very basic concepts embodied by the Act. On the 3rd day of May, 1984, in testimony before the Senate Committee on Labor and Human Resources, DHHS Assistant Secretary for Health, Edward J. Brandt, Jr., M.D., stated:

> " * * * the bill[37] . . . has major weaknesses which make it impossible to support. Of special concern

---

[36] By this time, ironically, the American Academy of Pediatrics was in opposition to certain aspects of the bill. *See* Argument Three section D, *infra*.

[37] The Table and Aids to Qualification and Interpretation were **jointly developed by the American Academy of Pediatrics and the Dissatisfied Parents Together.** In 1984, Jeffrey H. Schwartz testified (1984 hearing record pp. 49-57) that the Table embodies another of the ten principles which Dissatisfied Parents Together forwarded to Congress:

> "The bill should contain safeguards to assure that the award of compensation will not depend on proof by the petitioners of (the elements of tort, *i.e.*, product and manufacturer identification, negligence, or defect in manufacture); or disproof of all possible alternative explanations for the child's injuries."

> are the broad list of compensable conditions . . . ***The bill establishes a strong presumption*** that the vaccine is responsible for essentially any adverse condition that happens after immunization unless there is uncontrovertible evidence of other causation." 1984 Senate hearing, pp. 13-15. (Emphasis added.)

The Department of Justice joined the anti-Table bandwagon in 1985. Robert L. Willmore, Deputy Assistant Attorney General, United States Department of Justice, responded to questions from the Senate Labor and Human Resources Committee, stating:

> "While simplification and cost savings are desirable goals, they should not come at the expense of credible decisionmaking. Many of the proposed compensation systems, however, suffer from that flaw. We believe, for example, that attempts to 'predetermine' causation would result in decisions that, while perhaps cheaper to arrive at, may be largely arbitrary and indefensible." 1985 Senate hearing, p. 231.

D. The American Academy of Pediatrics Cannot Deny That the Table Means What It Says.

At the 1984 Senate hearings, Dr. Martin H. Smith, President-Elect of the American Academy of Pediatrics, spoke "in strong advocacy" of the Hawkins bill. Dr. Smith advocated "as simple justice for children that if injury occurs . . . the public owes to the victim a simple, direct and prompt compensation" (1984 Senate hearing, page 145). In written materials submitted[38] into the hearing record, the AAP stated

---

[38] The AAP also filed a discussion of the costs of the Program, and **admitted then** that the compensation to be awarded under the Act would financially benefit the Federal government' social programs. At page 239 of the 1984 Senate hearing record, the AAP states,

> " * * * To the extent that victims choose the legislative route, the vaccine-injury costs, such as medical, education, and training expenses for immunization victims, that presently are paid by entitlement and social programs, will be shifted to the compensation fund, reducing the burden on federal programs."

> "The Academy has spent a number of months negotiating with the parents' group, Dissatisfied Parents Together, to reach agreement on the provisions of this bill. We found they had many strong concerns that went beyond our original concept of the legislation. We came to realize that their concerns were real and based on their difficult experience and they similarly came to appreciate the validity of some of our concerns. We know that there are other interested parties that will speak out on this subject and they should be heard. We are confident that out of these hearings can come an excellent piece of legislation that can improve our management of vaccine injuries." (1984 Senate hearing, page 151.)

Dr. Smith's written testimony stated:

> "While this could be looked upon as simple compensation legislation to take care of another instance of product liability, let me stress that the justification lies in the fact that this is the *only* product, to my knowledge, whose use is required by law. This is a unique situation that is deserving of special remedies." (*Id.*, page 152, emphasis in the original.)

In oral, question-and-answer testimony, Dr. Smith went on to favor adoption of the Vaccine Injury Table, and he stated that "there is some advantage in having it in the legislation. There is incorporated in the legislation opportunity for alterations in the table with additional time and experience." *Id.*, page 255.

Then in 1985, at Senate hearings again, Dr. Smith testified that the AAP had already been eight years advocating a Federal vaccine compensation program. 1985 Senate Hearing, page 321. Dr. Smith stated that the AAP objective was "nothing more nor nothing less than simple justice for the children of this country." *Ibid.* Dr. Smith went on to explain the Table:

> "From the beginning of our advocacy of a compensation system, a prime concern has been to ensure the prompt and equitable compensation of those who are truly injured, but at the same time

sort out those temporally associated events as completely as possible if they could mimic vaccine reactions.

"The table of injuries, appearing in this legislation, is our attempt to serve that purpose. It represents the advice of Academy experts as to the types of serious reactions possible from each vaccine and the limits of time that can be reasonably allowed for the appearance of these reactions after each dose.

"It may never be possible to perfectly sort these claims, but we maintain that this type of mechanism can bring us closer to the ideal judgement of the claims, as they will arise.

"We hope that this type of table can be included in the legislation, rather than wait the indeterminate time of rulemaking. The legislation provides a mechanism for modification of the table as experience creates the need." *Id.*, page 323, emphasis added.

Dr. Smith went on to state that in evaluating proposed legislation that the "first and most important criterion" was providing "a better and more prompt form of justice for children." *Ibid.*

Also in 1985, the AAP presented both written testimony and responses to questions from Senator Orin Hatch (R. Utah). In the written testimony, the AAP stated of the Table:

> " * * * With the assistance of our own pediatric epidemiologists and neurologists, and with the concurrence of the parent's group, S. 827 contains a scientifically defensible and equitable table of compensible events . . . which have in the past been demonstrated to have a causal connection to the particular vaccine in issue . . . " (1985 Senate hearing page 330).

In the responses to Senator Hatch, the AAP also defended the Table, denying Administration assertions of inflexibility. The AAP stated that the Table is "a scientifically sound listing of recognized reactions." *Id.* at 335.

Finally, though, as the bill neared enactment, the AAP pulled up short. In testimony reproduced in the record in its

pre-scripted form, Dr. Smith stated that with one exception the Table, supported by expert medical and scientific opinion, should be adopted. This "one exception" was that the Table carried the presumption of compensability to sequela of Table reactions, **and** that the concept of "significant aggravation" was included in the Table (1986 House hearing, page 130). Even then, the Academy had no objection to significant aggravation compensation "unless clear medical evidence indicates otherwise." The Academy suggested an amendment to the provisions affording significant aggravation compensation, which would award it "unless there is persuasive medical evidence that the injury was not caused by the vaccine." *Id.* pp. 130-31.

The Secretary's *amicus*, therefore, as much as the Secretary, cannot assert in good faith that the Table was not enforced in the Court of Appeals **exactly** as Congress intended. And shame upon the Academy, in the case of Maggie Whitecotton, for loosing sight of its major goal in supporting this legislation, of simple justice for children.[39]

E. The Federal Circuit Consistently Follows the Rule Below, and Correctly Holds That the Government Must Satisfy an "Actual Causation" Burden of Proof.

The Secretary seeks the repudiation[40] of the recent case decision of the Court of Appeals in *Koston v. Secretary of DHHS*, 974 F.2d 157 (Fed Cir. 1992), which sets forth a straightforward reading of the Act:

---

[39] The Academy has also, apparently, failed to consider its other goal – shielding vaccine makers and doctors from tort litigation. More, not less, tort litigation would flow from the statutory construction the AAP urges on the court.

[40] The Secretary **advocated Koston** in its brief for rehearing before the Court of Appeals. While she says here that *Koston* is illuminative of "consequences that congress could not have intended" (Pet. Br. p. 33), the Secretary below accepted *Koston*, attempted to distinguish this case, and stated, ***the rejection of an idiopathic alternate cause was well grounded in the Vaccine Act."*** Brief in Support of Rehearing, p. 12.

> " * * * * Section 300aa-13 (a) (2) (A) defines unrelated factors as ***not including*** 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.' Since the word 'or' is used with both the adjectives (idiopathic, unexplained, unknown, or hypothetical) and the nouns (cause, factor, injury, illness, or condition), ***it is apparent that an unrelated factor is not an idiopathic illness***, an unexplained illness, or an unknown cause. As Koston says, 'The statute is plain enough. An "idiopathic" condition, or a condition with an "unknown cause", is not a "factor unrelated" to the administration of the vaccine.' " *Id.*, 974 F.2d at 160, emphasis added.

The *Koston* court recognized that "(o)ur task is purely one of statutory interpretation." *Id.*, 974 F.2d at 160. The court acknowledged that "Section 300aa-13 (a) (1) (B) of the Vaccine Act bars compensation if there is 'a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine.' " *Ibid.* The failure of the Court of Federal Claims on review below, and the consistent failing of the special masters, never more evident than in this case, is to recognize just how limited and narrow Congress intended the search for alternate cause to be.

The *Koston* decision as quoted above from 94 F.2d at 160, *supra* explicitly stands for the proposition that the use of the word "or" confines inquiry; if it requires that the special master observe the entire list of etiologies which cannot be factors unrelated, it follows that the special master must follow and be limited by the list which can.

Moreover, in *Koston*, at page 161, the Court of Appeals states:

> "By the plain words of the statute, we have an unknown cause and seizures occurring within three days, the period the Vaccine Injury Table sets for recovery. 42 U.S.C. § 300aa-14. ***That is the end of our inquiry***, although we are also satisfied that this interpretation is consonant with the purpose of the statutory scheme . . . " (Emphasis added.)

Another decision from the Court of Appeals, *Knudson v. Secretary of DHHS*, 35 F.3d 543 (Fed. Cir. 1994) furnishes an important source of proper interpretation of the Act and its language.

The Secretary and her *amicus* ally cite[41] *Knudson* for the proposition that the statutory concept of "idiopathic" is not to be taken literally. The Academy states, "the court held that the government could defeat a compensation claim by offering proof of an alternative cause of injury – there, a viral infection – although the cause of the (viral) infection was unknown." This is a word game. The cause of a viral infection is a **virus**. The implication that a virus is "idiopathic" is unsupportable. The Court correctly so held.

Moreover, – and this is the key – an infection is within the statutory list of factors unrelated which **is** allowable to rebut the presumption of compensability in a Table case. Why, then, did the Secretary not prevail in *Knudson*? It is because she could not **prove** that the viral infection caused the encephalopathy.

Knudson stands for the eminently correct proposition that the government's burden to prove alternate causation, once a Table injury has been proven, is the same as an off-Table petitioner's burden to prove actual causation. *Id.*, 35 F.3d at 548-549 ("proof of actual causation in fact generally requires 'proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury . . . ' [citations omitted]. . . . thus the government may defeat a petition with a theory of viral infection so long as it proves that there was in fact a viral infection ***and that the viral infection 'in the particular case [was] . . . principally responsible for causing the petitioner's illness . . . '*** " Emphasis added.) The issue on review was one of law, *i.e.*, the legal sufficiency of the actual causation showing. And the Court rejected **exactly** the same theory of causation as Dr. Evans forwarded herein, namely that because viral infections (or "chronic brain syndrome") is so much more common than vaccine injury, then viral infection "had to be the cause." *Id.* at 550.

---

[41] Secretary's Brief at 28, 29-34, Academy's Brief at 9-11.

Finally, the *Knudson* court correctly enforced the Table presumption of causation of "sequela." At page 550, the court stated, "there is no requirement under the Vaccine Act that petitioners prove that DPT caused symptoms or injuries ***other*** (emphasis in original) than the Table injury or the injury complained of."

Although it is the rule that when an erroneous standard prevails at trial, it is normally not for the appellate court to decide the case (but rather to remand), this is not the case where only one result can follow. See, *Pullman-Standard v. Swint*, 102 S.Ct. 1781, 456 U.S. 273, 72 L.Ed.2d 66 (1982). This Court should affirmatively rule in Maggie Whitecotton's favor.

ARGUMENT FOUR: MAGGIE WHITECOTTON'S CASE DOES NOT BRING INTO PLAY THE STATUTORY CONCEPT OF "SIGNIFICANT AGGRAVATION."

A. There Must be Preexisting Symptoms Before There is a "Preexisting Condition."

It is simple with reference to the Act to demonstrate the absurdity of the government's characterization of a certain size small head[42] in any event as a "preexisting condition." It is shown by the fact that virtually no compensation would be available for a person with "symptoms" identical to Maggie's state before her third vaccination. She had **no** neurological[43] manifestations.

That is, 42 U.S.C. § 300aa-15 (a) contains the shopping list of remedial measures, the cost of which are used to calculate the compensation. None of these address the problems of the person with a small head. Such a person **has no**

---

[42] In the course of the petitioner's arduous but successful litigation in the case of *Ciotoli v. Secretary of DHHS*, 18 Cl. Ct. 576 (1989), the Department of Justice argued that the child's head was **too large** for him to be normal.

[43] Quite clearly the head size itself is not the type of "condition" which the Act refers to as neurological. See, *e.g.*, the description of encephalopathic symptoms in § 300aa-14 (b) (3) (A), and note the requirement for ***significant injury*** to or ***impairment of function*** of the brain, which, like "abnormality," must be ***acquired***. (Emphasis added.)

problems. The Act contemplates compensation for services which are required when a child is developmentally disabled. It only follows that something is not a preexisting condition which makes a child different, if the child is **not** in need of such services.

Simply put, "significant aggravation" as used in the statute requires a preexisting **disability**. Maggie Whitecotton had no health problems of a compensable variety for "deterioration," nothing to be made "worse," and no disability or pain to be made "markedly ***greater***." That which does not **exist** cannot be made "greater." *See* the definition of significant aggravation at 42 U.S.C. § 300aa-33 (4) (Pet. Br. p. 6). This point – that a condition must be already clinically active to be "aggravated," is made in countless cases from compensation law systems. *See, e.g., Matter of Compensation of Aquillon*, 653 P.2d 264 (Or. App. 1982); *Reynolds v. Ruidoso Racing Assn, Inc.*, 365 P.2d 671 (N. Mex. 1961); *Hoppin v. Industrial Commission of Arizona*, 692 P.2d 297, 304 (Ariz. App. 1984); *Silva v. New England Group, Maremount Corp.*, 444 A.2d 343 (Me. 1982); and *Self v. Starr Davis Co.*, 187 S.E.2d 466 (N.C. 1972).

B. "Significant Aggravation" Only Applies To Clinical Illnesses.

The Secretary complains in her brief that in the case of *Cepeda v. Secretary of DHHS*, Case No. 90-2664 (Fed. Cl. Spc. Mstr. July 12, 1994) one special master has stated, "significant aggravation 'need no longer be referenced in the resolution of table cases.' " Pet. Br. at 23-24. This interpretation need not be made of the rule below. Rather, the commonsense argument relied upon by petitioners in *Cepeda* was founded exclusively in the statute. The *Cepeda* court, nonetheless, may have the **first** to give a presumption of causation in a true significant aggravation[44] case! The import of *Cepeda*

---

[44] Other than the fact that the Table case was one of significant aggravation, the *Cepeda* fact situation is analytically identical to that described by the Federal Circuit in *Knudson*. There was a possible virus infection, but the government could

(or perhaps more accurately, the import of *Whitecotton* **to** *Cepeda*) is merely the enforcement of the concept of "significant." But Congress provided for "significant aggravation" to serve its purpose of promoting confidence:

> "While it is true that some children, because of their physical condition, are more likely to react to a vaccine, vaccine reactions are not completely foreseeable. There is today no "perfect" or reaction-free vaccine on the market. A relatively small number of children who receive immunizations each year have serious reactions to them. But ***it is not always possible to predict who they will be*** or what reactions they will have. ***And since State law requires that all children be immunized*** before entering school, most ***parents have no choice*** but to risk the chance – small as that may be – that their child may be injured from a vaccine." H.R. 99-908, page 6, reprinted at page 6347, USCCAN 1986, emphasis added.

Two completely different scenarios are lumped together by the *Misasi* doctrine, as applied by Special Master Baird at trial below. The first is where a latent disorder (e.g., Tuberous Sclerosis Complex, as in *Costa v. Secretary of DHHS*, 26 Cl. Ct. 866 (1992)) might be seen as "triggered" by a vaccine[45]. The second is where an already symptomatic condition is made, allegedly, significantly worse. In looking at the legitimacy of the doctrine, Worker's Compensation law provides the answer: such "lighting up" is **cause**, not aggravation. *See*,

---

not prove that it caused the encephalopathy. The special master, with the evidence seen "in equipoise," (*see Knudson*, 35 F.3d at 550) ruled for petitioners.

[45] See also, *Huber v. Secretary of DHHS*, 22 Cl. Ct. 255 (1990) compensation awarded, Case No. 89-72V, Special Master Decision August 6, 1990, and *Wilson v. Secretary of DHHS*, 23 Cl. Ct. 169 (1991) (appealed on other grounds), compensation awarded, Case No. 89-65V, Special Master Decision January 22, 1991. In these cases, the latent condition of Tuberous Sclerosis Complex was seen as no defense, and the injuries seen as "onset" injuries. Contrary to the new, interim rule of *Costa*, "significant aggravation" should **only** apply, even to TSC cases, where a child has **actually** seized before the shot in question.

Reynolds v. Ruidoso Racing Association, *supra*, ("aggravation" implies previous disability, legal cause is the concurrence of the injury and the preexisting factors, statutory requirements of aggravation need not be literally applied). *Accord*, *Hoppin v. Industrial Commission of Arizona*, *supra*, (where there is no preexisting disability, there is no apportionment; the employer "takes his employee as he finds him.") **All** resulting disability, when the preexisting **latent** condition combines with the injury, is "in legal contemplation the proximate result of the industrial injury." *Id.*, 692 P.2d at 304. *See also*, *Matter of Compensation of Aquillon*, *supra*, and *Silva v. New England Group, Maremount Corp.*, *supra*.

ARGUMENT FIVE: THE COURT OF APPEALS MUST BE AFFIRMED WITH A DECISION WHICH HONORS THE EXPRESS STATUTORY LANGUAGE AND LEGISLATIVE INTENT

The functions of statutory interpretation are to be delineated before an exercise in interpretation is undertaken. To interpret law is to make law. *See*, generally, 2A *Sutherland Statutory Construction* (5th Ed.) § 45.03. Nonetheless, the courts are in the business of statutory interpretation, and **if interpretation is necessary** the government has correctly invoked the all-encompassing standard, "the intent of the legislature." *Sutherland*, *supra* at § 45.05, states that cases setting forth this rule are "so numerous that it would serve no purpose to attempt to cite all of them."

This is not to say that caution is inappropriate. The scholarship on the subject is such as to suggest a prime directive: As stated by Holmes, "we do not enquire what the legislature meant, we ask only what the statute means." *Id.*, at § 45.07, page 31, pointing out the concurring opinion of Justice Jackson in *Schwegman Bros. v. Calvert Distillers Corp.*, 341 U.S. 384, 95 L.Ed. 1035, 71 S.Ct. 745 (1951) and citing to Frankfurter, Some Reflections on the Reading of Statutes, 47 Colum. L. Rev. 527 (1947).

Turning, then, to the question of whether and how a certain word (*e.g.*, "idiopathic") should be construed, we find in Sutherland several principles.

"The policy favoring conventional meanings and general understanding over obscurely evidenced intention of the legislators is supported in the oft repeated premise that intention must be determined primarily from the language of the statute itself. *Id.*, § 45.08, citing *Flora v. United States*, 357 U.S. 63, 2 L.Ed.2d 1165, 78 S.Ct. 1079 (1958). And of course this philosophy is more concretely expressed in the "plain meaning rule," explicated in Sutherland at § 46.01. Throughout Chapter 46, we find the nuances of this rule; nowhere, even in § 46.07 ("Limits of Literalism"), is there support for the notions of interpretation forwarded by the Secretary and her *amicus*, with regard to the concept of "idiopathic." The consideration that should most easily tip the balance in favor of Maggie Whitecotton, and similar petitioners (*e.g.*, Jenna Koston or Debra Ann Knudson), is the principle that each word of the statute should be given effect. *Id.*, § 46.06.

A. There is No Legitimacy in an "Interpretation" Exercise.

The Secretary seeks two affirmative rulings by this Court, both of which involve statutory "interpretation" or "construction." Ultimately, the statutory interpretation argument which is the very heart of the appeal comes down to the meaning of **only two** separate words. The first of these words is "first," as in "first symptom or manifestation of . . . onset ***or . . . significant aggravation***[46]."

The second of these words is "idiopathic," as in "***factors unrelated . . . does not include*** any idiopathic, ***unexplained, unknown, hypothetical, or undocumentable cause . . .*** "

---

[46] 42 U.S.C. § 300aa-14 (a) (emphasis added). Query, if one of the first symptoms in a Table case can be the first symptom in the significant aggravation of a preexisting condition, what more should the Vaccine Court look for, than a child who was hospitalized with seizures? Does not the contemporaneous diagnosis of "immunization encephalopathy" imbue Maggie Whitecotton's seizures with enough legal dignity to satisfy the criteria for "first" symptom of apparent vaccine injury? Should not the burden shift to the Secretary?

"Idiopathic" is the **only** "medical[47]" word in the list of prohibited factors unrelated. But the Secretary wants an interpretation **against** petitioners. She wants the meaning and application somehow limited. With the word "first," the Secretary wants a **strict** application, again, to favor the government and to work against compensation.

It is axiomatic that congress is presumed to have intended the omission of words that it could have carried over from other parts of the same legislation, in order to effect the same meaning. Congress **could** have left the door open to other, non-specified "factors unrelated," by stating that "if an encephalopathy was caused by infections, toxins, trauma, metabolic disturbances **or other factors unrelated**, it shall not be considered a condition set forth in the Table." The failure to include such as the emphasized language in 42 U.S.C. § 300aa-14 (b) (3) (B) must be considered to be intentional. *See, Russello v. United States*, 464 U.S. 16, 23, 104 S.Ct. 296, 300, 78 L.Ed. 2d 17 (1983).

There has been no common-sense discussion of the provisions defining "factors unrelated." No questions have been answered regarding the effect of the **other** limitations on "factor's unrelated." Is not the government defenses of "chronic organic brain syndrome" embraced by the expressions "hypothetical" or "undocumentable?[48]" What type of idiopathic syndrome is **not also** to be regarded as "unknown?" How can the court enforce the concept of "unexplained cause," if it redefines "idiopathic?"

The meanings of the other words of § 300aa-13 (a) (2) (A) are revealing. While not to belabor the point by defining the prefix "un," petitioners would point out that one dictionary meaning of "explain" is "To offer reasons for or a cause

---

[47] It should be pointed out that the "medical" concepts of "residual seizure disorder" **and** "encephalopathy" are given broad meanings which are liberal to the concept of finding compensable injury. It would seem curious that Congress would expressly **re**-define such terms, with a broad scope, if – as argued by the Secretary – it **also** "intended" that the word "idiopathic" be interpreted **not** to have the **normal** meaning which would also serve the same end.

[48] The Court of Appeals held the defense to be "speculation."

of; answer for; justify." *American Heritage Dictionary of the English Language* (1978). And the same tome defines "document," the verb, as "to support (an assertion or claim for example) with evidence or decisive information."

Similarly, "hypothetical" carries a definition of "suppositional, conjectural, uncertain[49]." And "unknown" – all but a synonym of "idiopathic" – is defined as "**a.** Not identified or ascertained; **b.** Not established or verified." *Op. cit.*

It is therefore clear that with these five statutory words, in a true sense, Congress stated that it **would not countenance** "idiopathic" factors unrelated. Upon saying this, Congress then reinforced the statement with four more synonymous modifiers. The argument is most specious which regards the Congressional intent as not being to give the word "idiopathic" its normal meaning.

B. A Condition Affected By Vaccination Cannot Be A "Factor Unrelated To Vaccine."

> "It cannot be said that the development of the disease as a result of the injury was not the consequence which might naturally or ordinarily follow as a result of the injury." 22 Am.Jur.2d 233, *Damages* § 283, citing *Chicago City Railway Co. v. Saxby*, 23 Ill. 274, 72 N.E. 755 (1904).

The concept of "relatedness" has been frequently examined by the courts. As a matter of law, the activity which is the central feature of a compensation plan needs only to have a nexus with the incapacity suffered in order for it to be "related." Therefore, any condition magnified, altered or acted on in any way by vaccination is not a "factor unrelated."

---

[49] Lest the Court feel constrained to honor the "factfindings" of the special master because the Court of Appeals did not disavow them, petitioners would point out that it did not **need** to. Because the Court of Appeals correctly decided that the Vaccine Court applied an erroneous standard of law, there was no need to address the factual concerns. But the Petitioners **did** furnish every reason for the factfinding to be rejected, including materials in support of a Rule 60 (b) motion. Many of these materials are included in the Joint Appendix. *Inter alia* these statements of medical fact witnesses specifically refute the misstatements in Maggie's medical records, all of which factors were relied upon by the Secretary's expert Dr. Evans.

Numerous cases have reached the courts in the area of service-connected disability for peace officers, firemen, and other public employees. Only where **no** connection can be shown between employment and disability (even in cases of heart attack, arthritis, tuberculosis, cancer, psychological disturbances, and the like), only where the underlying weakness is seen as the **sole** cause, may the claim legally be rejected. See, generally, the annotations at 85 ALR 2d 1048, 7 ALR 4th 799, and 12 ALR 4th 1158; *see also Bolinger v. Division of Retirement, State Department of Administration*, 335 So.2d 568 (Fla. App. 1976)[50].

Ultimately, the presumption created by "Table Time" under § 300aa-14 is the basis for finding that a condition is "related" to vaccine. It is an illegitimate undermining of the legislation for the Secretary to deny this, and to sponsor a witness who does not believe that vaccine injury is possible. To such an expert as Dr. Evans, **any** condition would be by definition a "factor unrelated" to what the government, his sponsor, insists is a harmless vaccine. This is bias, and renders the opinion valueless. *cf. Bradley v. Secretary of DHHS*, 24 Cl. Ct. 641 (1991). Testimony that a presumed injury "cannot occur" does not rebut a statutory presumption of injury. *Pinion v. Board of Retirement*, 152 Cal. Rptr. 383 (1979 5th Dist. App.); *see also, Bunting v. Secretary of DHHS*, 931 F.2d 867, 873 (Fed. Cir. 1991).

C. The Vaccine Act Must Be Harmonized With Compensation Law

The Court of Appeals ruling herein is philosophically consistent with the most mainstream elements of American law: The injured party is taken as he or she is found prior to the injury; the burden is not to be placed on the innocent injured party to apportion between the wrongdoer and some other possible cause; to hasten injury is to cause it; to interpret the law is prohibited where its meaning is clear. *A fortiori*, the nature of the Act as a "no-fault" compensation Act calls for this court to affirm the Court of Appeals ruling.

---

[50] *Bollinger* also points out that an impact on the compensation fund is an issue for the legislature, and not the courts.

A very instructive Decision, from the Office of the Special Masters, is virtually the only such **explicit** statement in the law of vaccine compensation to thoughtfully consider these mainstream philosophies. Petitioners commend the court to the case of *Costa v. Secretary of DHHS*, Case No. 90-1476V (Cl. Ct. Spc. Mstr. February 26, 1992)[51].

The Secretary refuses to acknowledge that liberal interpretation doctrines from compensation law, or even that **any** doctrines from other compensation laws, were "intended" by Congress for the Vaccine Program[52].

The huge body of American compensation law clearly establishes the reality and compensability in the "lighting up" or "triggering" of latent pathologies[53] and diseases, from diabetes to tuberculosis, from heart disease to congenital back weakness. And compensation law is instructive as to the necessary nexus between the contemplated source of compensable injury (whether it be

---

[51] This case was remanded by a Judge of the Claims Court to the special master, on the government's interlocutory appeal, by virtue of the previously-cited *Costa v. Secretary of DHHS*, 26 Cl. Ct. 866 (1992). The case has not been passed upon in the Court of Appeals, although the government announces the intention to appeal. But damages proceedings (the petitioners prevailed both initially and on remand) continue in the Office of Special Masters. For reasons discussed herein in Argument Four, *supra*, Petitioners disagree with the order of remand, to the extent that it requires the application of "significant aggravation" doctrine to the case of a child who was in **perfect** health prior to the shot.

[52] See the discussion at 2A *Sutherland Statutory Construction* § 45.10 (5th Ed.), relating to the concept of "legislative common law." This concept is at the heart of the use of such terms as "no-fault." Legislative bodies have a particular and very concrete scheme in mind when the idea of a "compensation act" comes up. Congress has enacted compensation laws before; this Court has reviewed them all.

[53] The *Costa* cases involve the compensability of vaccine injury in children who are born with the condition known as Tuberous Sclerosis Complex, or TSC. TSC is a condition known to involve mental retardation and seizures, but **never** to involve mental retardation **without** seizures. Approximately two-thirds of the population with TSC are believed to be seizure-free and mentally normal. And permanent vaccine injury is scientifically estimated to be **3000 times more common** in the TSC community than in the "normal" population. Miller, *et al.*, Unreviewed Technical Report, "Parent Reports of DPT Seizure Reactions in Individuals with Tuberous Sclerosis Complex." University of Akron, January 1995. Congress did not give the slightest hint that it did not intend to protect even these children, when it crafted the Act.

employment in general, exposure to certain conditions such as coal dust, or any other subject of compensation legislation) and the ultimate sequelae, in order to qualify for compensation.

Finally, then, Respondents urge the Court to follow the approaches taken in its previous cases which are at the heart of the "interpretation" issues here.

Thus, as in the recent decision of *Brown, Secretary of Veterans Affairs v. Gardner*, ___ U.S. ___, 63 USLW 4035, 1994 WL 687055 (Case No. 93-1128, decided December 12, 1994), this Court should "naturally read" the statutory language, and resolve interpretive doubt in Maggie Whitecotton's favor. *See, King v. St. Vincent's Hospital*, 502 U.S. 215, 220-221, 112 S.Ct. 570, 574, 116 L.Ed.2d 578 (1991), fn. 9.

Here, as in *Good Samaritan Hospital v. Shalala*, 508 U.S. ___, ___, 113 S.Ct. 2151, 2157, 124 L.Ed.2d 368 (1993), the Court must again pronounce that "the text and reasonable inferences from it give a clear answer against the government, and that, as we have said, 'is the end of the matter.' " *Brown, supra*.

As stated by Justice O'Connor, writing for the majority in *Director Office of Worker's Compensation Programs, U.S. Department of Labor v. Perini North River Associates*, 103 S.Ct. 634, 459 U.S. 297 (1983), it has been "long held" that the compensation statute is to be liberally construed, "in conformance with its purpose, and in a way which avoids harsh and incongruous results." *Id.*, 101 S.Ct. at 646.

> "***The system is intended*** to be expeditious and fair. It is also intended ***to compensate*** persons with recognized vaccine injuries ***without*** requiring the ***difficult individual determinations of causation*** . . . " H.R. 99-908, 99th Cong., 2nd Session, pt. 1, page 12, *reprinted* 6 USCCAN 6344, 6353 (1986), emphasis added.

Any resolution of the ambiguity between permissive and mandatory language in the qualifications and aids to interpretation must be accomplished in a manner consistent with the overall purpose of the act; any proper interpretation of the terminology in the Act will most clearly be consistent with compensation for Maggie Whitecotton.

CONCLUSION

For all the foregoing reasons, the decision of the United States Court of Appeals for the Federal Circuit should be affirmed, and the case remanded to the special master for a prompt determination on compensation owed to Petitioner Maggie Whitecotton.

Respectfully submitted[54],

ROBERT T. MOXLEY*
RICHARD GAGE
GAGE & MOXLEY
623 West 20th Street
Post Office Box 1223
Cheyenne, Wyoming 82003
(307) 632-1112

PROF. PETER H. MEYERS
Vaccine Injury Project
National Law Center
George Washington University
2000 G Street, Suite 200
Washington, D.C. 20052
(202) 994-7463

JOHN S. CAPPER IV
BERRY, CAPPER & TULLEY
P.O. Box 429
Crawfordsville, Indiana 47933

Counsel for Respondents
*Counsel of Record

---

[54] Counsel appreciate the substantial research and drafting assistance provided by Lynn A. Brazinski, Joanne M. Hatem, M.D., J. Kirk Ogrosky, Heather M. Zimmerman, and Todd P. Forster, all of whom are law students at the National Law Center of the George Washington University.